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13. ABSTRACT (Maximum 200 Words) This project is a prospective study of women who are at high risk for early-onset breast cancer, and their husbands and siblings. Proband women are assessed at entry into the study, immediately before receiving results, and 2 months, 6 months, and 12 months after receiving results. Among women who do not receive test results, yearly assessments are administered to track changes in functioning over time. The main objectives of the study have been to describe psychological functioning among high-risk women and their families; to evaluate the performance of screening instruments in detecting clinical depression; to describe social support processes among high-risk women; and as follow-up data become available, to assess the impact of genetic testing on women and their families. In general, both extensive baseline data and preliminary follow-up data suggest that women and their families manage the process of genetic testing well, exhibiting relatively low levels of distress and worry, and reporting few negative effects of testing. Ongoing analyses are beginning to clarify predictors of health behaviors, risk perception, response to testing, marital functioning, and other indicators of adjustment. Future analyses will clarify causal relationships among personality, functioning, and other variables, as follow-up data become available.				
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INTRODUCTION

This project involves a prospective study of women who are at high risk for early-onset breast cancer and their families. The project tracked four interrelated groups: (1) approximately 500 proband women who have a risk for early onset breast cancer based on two or more family members being affected by cancer, and who will be among the first persons to have access to testing for alterations of the BRCA1 and BRCA2 genes; (2) the spouses of the approximately 400 women who are married; (3) a stratified random sampling of 120 of the women's unaffected sisters (those who have not been diagnosed with breast cancer); and (4) 80 brothers. Key variables include proband women and family members' stress and social support processes, including cancer-related stress and support; psychological distress and psychiatric morbidity; marital and family functioning; psychological characteristics presumed to affect the women's information-processing, decision-making, and subsequent adjustment; the at-risk women's intentions to seek predictive testing and anticipated outcomes and plans for use of the information; relevant attitudes, beliefs, and expectations; and current surveillance and adherence behaviors. Initial assessment of the proband women is by self-report questionnaires and telephone interviews. Subsequent reassessments of proband women's current cancer-related stress, support and beliefs, attitudes and intentions, distress, and psychiatric morbidity will also be by telephone interview and questionnaire. Husbands and siblings are assessed by self-report questionnaires. The proband women, spouses and siblings are then reassessed as the option of predictive testing is made available to the individual women. A second reassessment of proband women occurs 8 weeks after test results are available. Follow-up assessments occur at 6 and 12 months for women choosing to receive their genetic testing results, and yearly for women whose test results are not yet available. The main objectives of the study have been to describe psychological distress and psychiatric morbidity among high-risk women and their families, to evaluate the performance of screening instruments in detecting clinical depression, to describe social support processes among high-risk women, and as follow-up data become available, to assess the impact of genetic testing on women and their families.

BODY

Background

Predictive testing is now available for mutations of both the BRCA1 and BRCA2 genes, known to increase risk for breast and ovarian cancer, and possibly other forms of cancer as well (e.g., prostate). Only about 5-10% of all breast cancer is believed to be hereditary in nature, but this figure could be as high as 20% for early onset breast cancer. Furthermore, it has been estimated that 15-45% of all families with multiple cases of breast cancer and as much as 80% of families with elevated rates of both early-onset breast and ovarian cancer carry mutations of either BRCA1 or BRCA2, although these figures may be somewhat lower in the general population than in the hereditary breast and ovarian cancer registries from which they were derived.

It has also been estimated that female carriers of mutations in BRCA1 or BRCA2 have a 50-85% lifetime risk of developing breast cancer. Carriers of BRCA1 mutations have a 20-40% lifetime risk of developing ovarian cancer, while the risk associated with BRCA2 is slightly lower at 15-20%. Male carriers of these altered genes are at somewhat increased risk for prostate and colon cancer, and male carriers of BRCA2 have a 6% risk of breast cancer. Cancer susceptibility conferred by BRCA1 and BRCA2 mutations is transmitted as an autosomal dominant trait which means that the mutations are inherited from either parent, and offspring have a 50% risk of inheriting the parental mutation. Options for women who test positive for an altered gene related to breast cancer include increased surveillance, prophylactic mastectomy and oophorectomy, and for some, participation in a chemo-prevention trial. None of these measures have proven to be entirely efficacious and all have known limitations, as recently noted by our investigator group (Eisen & Weber, 1999).

The current project has been tracking women and their families from well-before genetic testing occurs up to 12 months after receipt of genetic test results. Testing has been offered to our research sample of high-risk women as part of a series of genetic linkage and mutation studies, and it has now also become available in the community. It is now estimated that approximately 1 in 1,000 people are carriers of mutations of these genes (Ford & Easton, 1995), and larger numbers can be expected to face the dilemma of whether to seek testing. Mutations of these genes are the first for which widespread genetic screening of asymptomatic persons for risk of late onset disease is appropriate, and the availability of the test raises some daunting and largely unprecedented issues. Women with positive family histories of breast cancer have expressed considerable interest in obtaining predictive testing. Yet little is known about the extent to which women who indicate they intend to obtain testing actually follow through with it. Furthermore, little was known about the anticipated benefits and drawbacks of knowledge of risk status which would influence their choice, or about the psychological and social costs to these women and their families of having access to such information. Positive findings could conceivably carry the threat of psychological and psychiatric morbidity for the women and family members, the disruption of family relationships, and the impairment of the women's surveillance and adherence behavior, but the degree of vulnerability and factors which identify

the individuals and families at greatest vulnerability have not yet been determined. Yet, negative findings or not obtaining information concerning risk status could also have detrimental effects on the women and their families.

In the absence of a large body of directly relevant prior research, we were faced with an urgent need for basic descriptive data concerning women at high risk for early onset breast cancer and their families, including their psychosocial assets and liabilities, their attitudes and beliefs, their intention to seek predictive testing, and their preparedness for possible results. We have now collected a substantial body of descriptive data about women with family histories of cancer, and their experiences with genetic testing, and have been disseminating these data (Coyne & Anderson, 1999; Coyne, Benazon, Gaba, Calzone, & Weber, 2000).

Recognizing the opportunity to build on our extensive baseline assessment with prospective data, we also instituted follow-up assessments at key points in the process of genetic testing. Now that the project has progressed to its third year, we are accumulating substantial follow-up data that allows us to track changes over time in participants' psychological and social functioning, cancer-specific perceptions and health behaviors, and other relevant factors. Our follow-up assessments also allow for describing how participants view the process of genetic testing, and the role that genetic testing has played in participants' lives. Furthermore, we have developed collaborative arrangements to ensure the predictive utility of our data in examining the long-term consequences of high-risk status and the availability of genetic screening to these women.

This project is a longitudinal study of a large sample of high-risk women and their family members who are among the first being offered the option of testing for BRCA1 and BRCA2. We originally anticipated assessing approximately 300 high-risk women, but have been able to expand recruitment to almost 500 women, due to the expansion of the Hereditary Breast and Ovarian Cancer registry. Women participating in our study receive in-depth baseline assessment by questionnaire and telephone interview. Initial assessments were started at the point of receipt of funding from the DoD. We sought additional funding through the Department of Defense Breast Cancer Initiative in order to complete initial assessments and to monitor women's progression through the process of genetic testing. We originally instituted assessments at 4 time points: when testing for BRCA1 becomes available to the individual women, within 8 weeks after receipt of results, and 6 and 12 months after testing.

Our sample is well described in terms of medical and family history. Our assessment instruments are psychosocial measures with immediate relevance to planning and the design of clinical protocols, as well as for their use in clarifying basic individual and family stress and coping processes. Variables assessed included attitudes and beliefs; personality traits; social support and family functioning; psychological distress and psychiatric morbidity; and decisions and behavior relevant to management of cancer risk. These measures will also allow estimation of psychosocial costs, if any, associated with the offering of testing, and modeling of intention to obtain testing and subsequent decision-making and functioning. The resulting

longitudinal data will have a direct application in estimating the need for services, refining appropriate clinical protocols, and suggesting requisite training for personnel providing services.

Additionally, given the importance of a woman's social support system, and the recognition that testing may be an event for husbands and family as well, this project incorporated a protocol for assessments of the husbands and siblings of participating women. Husbands and siblings are assessed by questionnaire before the proband woman receives her results, and are reassessed at 6 months following the woman's receipt of results.

The first overall objective of this study has been to assess psychological distress, current and past psychiatric disorder, and functional impairment in women at high-risk for breast and ovarian cancer who are anticipating the prospect of genetic testing. Establishing base rates of distress and impairment permits us to evaluate the mental health needs of women anticipating testing, and it also serves as a first step in evaluating the incremental distress associated with receipt of results.

The second objective has been to compare the two groups of women within our sample: women who had been previously diagnosed with breast cancer, and women who had not been affected at the time of assessment. Initial differences between the two groups are important for the evaluation of the extent to which unaffected women subsequently develop characteristics like those of affected women upon receipt of findings that they carry the altered gene. On the other hand, it might prove to be the case that heightened awareness of high risk status among unaffected women has already resulted in comparable levels of distress and disorder.

A third objective has been to describe social support processes in the experiences of women at high risk for cancer and their families. This objective will continue as the women progress from baseline assessment through the opportunity to obtain results, and beyond testing to follow up periods. We have been particularly interested in the involvement of husbands and female family members in proband women's decision making concerning cancer risk management and whether to get testing. Spouses are usually the most important source of support for married persons (Brown & Harris, 1978; Coyne & DeLongis, 1986). Yet, the women in our study are members of high risk families, with first-degree female relatives in similar predicaments. The support and information that close female relatives provide, how these relatives cope with their own dilemmas, and the decisions about testing they make are likely to have profound effects on the high-risk women. It may be that as a result of the mobilization of social support around the shared risk of cancer, female relatives come to have more influence on the distress levels of these women, and the spouses correspondingly less. An understanding of these support processes has a practical importance in the design of educational, counseling, and follow-up protocols for these women and their families.

A fourth, overarching objective has been to track psychosocial changes among participants through the process of genetic testing being offered to them. As a result of our ongoing assessment efforts, we anticipate having sufficient follow-up data in the near future to conduct initial longitudinal analyses, both for proband women and for their husbands (where applicable) and their sisters. These analyses can begin to evaluate

changes with time in psychological distress, breast cancer worry and worry-related functional impairment, risk perception, screening behaviors, and other relevant factors. We also have rich descriptive follow-up data about the impact of genetic testing on the lives of high-risk women and their families.

Procedure and Accomplishments to Date

Years 1 & 2

As reported in two previous annual reports, we have successfully met our objectives during the first two years of the study. Expansion of the Hereditary Breast and Ovarian Cancer Registry from which subjects are drawn allowed recruitment of a larger sample for baseline assessment than previously expected. This was fortuitous because preliminary testing of blood samples from women already affected by breast and ovarian cancer in high risk families has now revealed that BRCA1 and BRCA2 account for less of the ostensibly hereditary breast cancer than previously predicted. At the present time, negative test results are generally not informative for women from families without a known mutation of BRCA1 or BRCA2. Identification of a particular mutation in a family member affected by breast cancer is a prerequisite for informative testing of unaffected family members. The implications of this are that many of the female family members of women in our sample will not be offered testing unless a mutation can be identified in our study participants. As noted below, there may also be an increased psychological burden on affected women seeking testing: Whether family members can be tested will depend on their results. Our now substantially augmented sample allows us to nonetheless have a more than adequate sample size and statistical power for women who do progress to a choice about testing.

We began to encounter delays during the second year in the offering of testing to individual women for a variety of technical and practical reasons. In response to these initial delays, and in anticipation of further delays, we designed an interim assessment to be administered if testing had not occurred within 1 year of baseline assessment. This interim assessment also served to reduce the burden of the baseline assessment by redistributing some of our trait measures to a second testing and it also involved the re-administration of measures of distress and other state variables likely to fluctuate over such a time period. As planned, women who progressed to the opportunity to get their results received these measures in their pre-counseling assessment. We also are taking advantage of a larger long-term follow-up study that will be recruiting women from the Hereditary Breast and Ovarian Cancer Registry who are found to have a mutation of BRCA1 or BRCA2. Additionally, an international sample of persons, both male and female, who have been found to have a mutation is being recruited and tracked over the long-term. Although the long-term Follow-up study was originally designed to track morbidity and mortality, we have added a psychosocial component using instrumentation developed in our present project. Furthermore, for women from our present sample who will continue to be followed, we will have the benefit of data collection started before they were found to be carriers of a mutation. For some purposes they will be separated for data analysis, but for other purposes they can be combined. This addition will very likely make our sample the largest data base concerning persons who have received genetic testing for risk of breast and ovarian cancer.

We continued to make progress in our second year. We continued data collection, refined our research objectives, and modified our instrumentation based on initial results. Our interim assessment allowed us to monitor state variables such as mood, and to obtain additional trait measures for women having more than a year elapse between initial assessments and actually being offered testing. We also responded proactively to a number of exigencies, including a lower uptake of genetic testing than anticipated and a greater proportion of noninformative results among women who obtain testing, but at a slower rate than had been planned. We enrolled additional participants in the study as new women were recruited to the larger Hereditary Breast and Ovarian Cancer Registry. As anticipated, women who were already enrolled in our sample are continuing to receive the opportunity to obtain testing. Some progressed to 6-month follow up during the second year. Based on initial results, we adapted instrumentation to better accommodate women who receive uninformative results.

For example, we refined our assessments of women's appraisals of the opportunity to obtain testing. Our scaling technique for this is an important methodological innovation in itself. We also have taken advantage of our interim assessment of the women in our sample and the initial assessment of their husbands to explore the role of social support processes in the apparent resiliency of these women. One hypothesis is that explicit awareness of the high-risk status of these families has led to the mobilization of support processes organized around this status. If this is so, women in the community seeking testing may not share this advantage. This should prove to be one of the many valuable points of comparison between our registry and community samples.

Year 3

During the third year of the project, we have continued to track women through the process of genetic testing, with some women now progressing to 12-month follow-up. Our recruitment and assessment of spouses and sisters has proceeded on schedule. We also submitted several manuscripts which have now been accepted for publication, focusing on psychological distress (Coyne, Benazon, Gaba, Calzone, & Weber, 2000), and social support (Coyne & Anderson, 1999). Copies of these manuscripts are included as Appendix A. We are in the process of analyzing data in preparation for a number of other manuscripts. One such manuscript expands upon the data presented in Coyne & Anderson, testing relationships between social support processes and psychological distress, and making use of the longitudinal data collected in this study. This project provides a unique opportunity to study the causal relationships among variables over time, in contrast to the majority of studies that are limited to making causal inferences from cross-sectional data. As more follow-up data become available, we intend to use causal modeling to clarify the temporal relationship between support and distress. Another set of analyses planned for publication involves describing perception of risk among women with a family history of cancer, and explaining how risk perception is formed and perhaps changed through the process of genetic testing. In a related study, we also plan to investigate the impact of genetic testing resulting in uninformative test results. Classic theory on predictive judgements (Rottenstreich & Tversky, 1977), the effects of framing

on judgements (van Schie & van der Pligt, 1995), and preliminary data from the current study suggest that there may actually be a psychological cost of participating in genetic testing when results turn out to be uninformative. With the imminent release of a new batch of test results, we expect to be able to address this question.

In addition to the continued progress we have made in collecting and presenting data, we successfully responded to important structural and technical challenges, and created opportunities from these challenges that were previously not available to us. The key structural change this year was the transfer of the project from the University of Michigan to the University of Pennsylvania. Until this year, the research teams at the two institutions had been collaborating from a distance, with the biomedical research team located in Philadelphia, Pennsylvania, and the psychosocial research team located in Ann Arbor, Michigan. Shifting the psychosocial component of the project to Philadelphia has allowed for an integration of these two important and complementary aspects of genetic testing, and has generated a number of collaborative research projects that take advantage of the diverse areas of expertise of research team members, and substantially increase the utility of data we have been collecting from our registry sample.

One such project addresses the issues of selection bias and sample representativeness in the Hereditary Breast and Ovarian Cancer registry sample. One would expect that women who volunteer to participate in a cutting-edge research project such as this might be an especially motivated, persistent, well-adjusted, and socially-supported group. Indeed our data show that women in the registry sample are remarkably free of psychological distress and psychiatric morbidity, and were socially advantaged in terms of education, income, and marital stability. This is consistent with other reports of high-risk women in research and clinical protocols, and of research participants during the identification of genetic markers for Huntington's disease. Although highly-select registry samples have been well described, we know virtually nothing about women in the general community who are in the process of seeking genetic testing. With increasing media attention, the continued research into genetic markers for cancer risk, and the promise of potentially modifying cancer risk, more women from the general population may seek or be offered genetic testing. Together with an oncologist extensively trained in epidemiology and biostatistics, we are in the process of implementing a large-scale study comparing the unique women in our research sample with two groups of women from the community. One group will come from an NCI Program Project studying women in the community (Brian Strom, Principal Investigator). In addition to capturing the experiences of women outside the highly-select registry sample, this project aims to describe the cancer risk experiences among African-American women who remain under-represented in the cancer registries.

Also, we are fulfilling our expectation for collaboration with University of Pennsylvania physicians, and recruiting a second group of women at high risk for cancer through the Cancer Risk Evaluation Program (CREP). Psychosocial and biomedical data from this study will allow comparisons between the cancer risk experiences of women in our registry sample and women seeking clinical (rather than research)

services through the CREP. We already have one paper in press, and have prepared another one concerning risk perception based on the CREP data.

Another project that developed as a result of our move to the University of Pennsylvania involves linking our psychosocial data with biomedical and other data for women participating in a randomized clinical trial of different methods of delivering genetic testing results. This project compares pre-test counseling and results disclosure by telephone with counseling and results disclosure conducted in-person at the physician's office. This study was instituted to address the inevitable changes in the genetic testing process as it moves from the controlled research setting to the larger community. This study aims to track the feasibility, acceptability, and effectiveness of different methods of delivering genetic testing services. Data from this new study will link with the extensive baseline psychosocial data already collected as part of the present study. This linking of data gives us the opportunity to test an aptitude-by-treatment interaction model (ATI), whereby specific participant characteristics are matched with particular types of interventions to achieve optimum effectiveness of services.

We are also expanding our Long-Term Follow-Up Study (LTF), begun last year as an adjunct to the current study. The LTF Study describes the long-term psychosocial functioning among women and men who have received genetic testing results through mechanism other than the University of Pennsylvania program.

Technical obstacles that began in the second year continued through the third year, resulting in delays in the actual availability of genetic testing results. Consultation with the University of Pennsylvania biomedical team suggests that the slow pace has been due in part to changing genetic testing technology. Specifically, laboratory technicians began to re-run assays to include an expanded range of exons, and began running southern blot assays on samples from families with low probability of mutations. We have been in close communication with the laboratory technicians and testing coordinator regarding these delays. The team now anticipates a flood of requests for test results as these new testing procedures are completed within the next 4-6 months, and as women are notified that their test results are available. The net results is that there will be a significant increase in the number of women receiving results during the fourth year, adding to our rich database of follow-up assessments. Our move to Pennsylvania will allow us the close collaboration required to manage such a large increase in patient flow. In the meantime, we continue to describe the experiences of women who have not yet received results through yearly interim assessments.

In addition to technological challenges, it also became clear during the second and third years of the current study that women who had initially expressed interest in testing are requesting their results at a much lower rate than anticipated. The decision to accept testing is not a simple dichotomous one, with many women either failing to respond to the opportunity for testing, or deferring a decision to an unspecified later date. Some of this declining of testing is passive, with participants simply not responding to letters notifying them that their results are now available, or by their not returning consent forms. This is quite consistent with past experience with testing of persons at risk for Huntington's disease, but it remains an important

phenomenon to study. Another investigator group has concluded that members of high risk families who decline testing in may suffer adverse psychological consequences (Lerman et al., 1997). However, we have shown that declining testing may represent a rational decision to defer testing when other stressors are present in women's lives (Coyne, Weber, & Sonis, 1999). We are currently refining a project that addresses such issues, and will specifically assess the experiences of women who have been offered testing but have not pursued receipt of their results. Our initial data provides us the opportunity to explore predictors of discrepancies between initial intention to obtain testing and actually pursuing receipt of test results.

Year 4

During the fourth year of the project, we continued ongoing data collection, and developed several adjunct projects to address areas of the genetic testing process that are not yet well understood. As part of our ongoing data collection, we continued to track women from pre-results through to post-results disclosure, as well as administering assessments to those women who still had not yet received test results. Women who had received results during the previous year completed 2-, 6-, and 12-month follow-up assessments this year. Also, completion of testing for mutations in BRCA2, and of re-testing many samples using more precise assays this year, made available test results to a large group of participants. As a result, the number of women progressing through to results-disclosure and post-results has increased dramatically this year.

As expected, our collaborations with the Cancer Risk Evaluation Program (CREP) at the University of Pennsylvania flourished this year. Together with the CREP group, we expanded the original WHS study to include comparing different methods of conveying genetic test results. Specifically, this study compares participants' experiences with traditional results-disclosure by a local provider to results-disclosure by a cancer risk counselor via telephone. This study is based on the recognition that genetic testing is no longer conducted solely in the context of research studies in academic settings, but is being delivered in less structured ways (e.g., by telephone) in the community by general practitioners. This adjunct study to the Women's Health Study will allow us the opportunity to compare participant outcomes given different methods of results-disclosure. An added benefit of this adjunct study is that it also allowed us to recruit new participants into our pre- and post-results assessments, increasing our study sample by about 100, including a small sample of male probands.

In addition, we focused our attention toward the large number of women who have not requested results of testing. Only a small proportion of women to whom results have been made available have actually followed through with receiving results. Clarifying the reasons why participants may not pursue results is an important aspect of understanding the barriers to genetic testing, and the degree of interest in predictive testing for cancer. In Year 3 of the project, we mailed an interim assessment to each woman who had not yet received test results. This year, in August of 1999, we mailed a second interim assessment to over 400 women who had still not received results. Adding these interim assessments to the thorough

assessment completed at baseline, we now have longitudinal data spanning three years. This allows us to track any changes in intentions to get test results among high-risk women who have not requested results, and other psychosocial issues such as marital satisfaction, coping, and life events that may be barriers to the pursuit of test results. Additionally, we conducted scripted follow-up phone calls to assess more specifically why women had not pursued getting test results. This has allowed us to distinguish between true decliners of test results and those who simply had not followed-through with getting results because of misunderstandings about the process, having lost the materials, or other reasons. These follow-up phone calls also helped to clarify the next step for those women who wished to get test results.

Together with the CREP group, we also produced several papers and presentations on the issue of risk perception and distress among higher-risk women seeking cancer risk counseling. Our research team presented two posters at The Eunice and Irving Leopold Annual Scientific Symposium and Retreat held in March, 2000 at the University of Pennsylvania, gave several paper presentations relating to psychological distress and the efficiency of screening measures, and submitted several empirical papers for publication in academic journals. Abstracts of these presentations, and copies of the manuscripts are included as Appendix A.

In the coming year, we plan to continue tracking participants' progress through testing, designing and conducting collaborative studies with the CREP group in order to maximize the efficiency and yield of data collection, and to report on the results of this large-scale, longitudinal study. Also in the coming year, we plan to investigate two areas relevant to genetic testing that have not yet been adequately explored. The first is the degree to which the findings about the psychosocial implications of genetic testing can be generalized to women who may be at high risk for cancer who receive cancer-related services in the community. Our sample of higher-risk women, while one of the largest and most diverse in the country, is made up mainly of caucasian women of higher-than-average socioeconomic status. Together with the CREP group, we have begun a desperately-needed study to evaluate the interest and impact of genetic testing among women with fewer social and financial resources than the typical cancer registry sample.

Also, because of the entrance criteria for the genetic linkage studies from which WHS participants were recruited, our sample comprises the largest group of women with uninformative genetic test results. Given decision-making theory and controlled experiments that manipulate the informativeness of data, the group of women receiving uninformative results may respond differently to test results than do women with more definitive results. In other words, the informativeness of results may be a better predictor of psychosocial outcome than whether the results are negative or positive for a known mutation. We will continue to explore these alternative explanations in our sample.

Methods

Women and their families participating in this study were drawn from the Hereditary Breast and Ovarian Cancer Registry originally established at the University of Michigan, but now housed at the University of Pennsylvania. There were two sets of criteria by which women could be included in the

registry. Unaffected women had to have at least two cases of either breast or ovarian cancer in their family, and affected women had to have at least one other family member who had been affected. A periodic informational letter to women enrolled in the registry made reference to the possibility of an impending longitudinal study of them and family members. To recruit subjects for the psychosocial component of the University of Michigan/ University of Pennsylvania study, a cover letter, consent form, and questionnaire were sent to eligible enrollees in the registry. After the baseline questionnaire and consent form were returned, subjects were contacted by telephone in order to answer any questions and schedule the telephone interview. If we received neither a questionnaire nor a mail-back refusal form, we called subjects, explained the details of the study, and offered to send another packet if necessary. At the point of actual receipt of funding, some of the women had already participated in the initial assessment and had been alerted to the possibility of their being asked to continue in a longitudinal study and to enlist family members. Women continuing to participate in the study are asked to solicit the involvement of spouses. Given the sensitive nature of risk information, concerns about confidentiality dictated that we utilize the women rather than contact the family members directly. We discussed the rationale with the women for their family members' involvement, underscored the voluntary nature of their choice whether to facilitate their family members' participation in the study, and if they so chose, ask them to provide names and permission to contact these relatives.

Consistent with the previous years' reports, our ability to track women and their families through the course of their being offered testing has been partially dependent upon them actually being given the opportunity to obtain results, and on their pursuing receipt of results. A number of factors affected the offering of testing in general and to specific individuals. Actual testing has proceeded slowly in our sample, and is almost entirely limited to affected individuals or to women in families with known mutations. As mentioned above, we anticipate a significant increase in the pace of disclosure of results during the fourth year, now that improvements in laboratory procedures for genetic testing have been incorporated into standard practice.

The nature of testing for genetic mutations on BRCA1 and BRCA2 is difficult, and the current study will allow us to describe psychosocial implications of the process of genetic testing for high-risk women and their families. Because the two genes are very large, analyses of these entire genes would be impractically labor intensive and expensive. Therefore, at the present time, the accuracy and informativeness of testing is hinged upon whether there is a known mutation of BRCA1 or BRCA2 identified in an individual in the family affected with either breast or ovarian cancer. When a known mutation is detected in a family, other members of that family can be tested specifically for that mutation, and testing results are informative (i.e., either positive or negative for the known mutation). If no such mutation has been identified in a particular family, then the only informative result for individual family members is when a specific mutation of BRCA1 or BRCA2 is identified. In the absence of a mutation having been found in a

family, a negative test finding for a given individual is not informative. This does not mean that the cancer is not associated with a cancer susceptibility gene, only that no such mutation can be identified at this time.

The net result of all of these considerations is that not every individual is appropriate for testing. For the University of Pennsylvania Hereditary Breast and Ovarian Cancer Registry, the decision was made to analyze first already collected blood samples from affected women. If an affected woman was found to have a mutation, testing is offered to her family. As in other hereditary breast cancer registries, it has been found that many ostensibly high-risk families do not carry a known mutation of BRCA1 or BRCA2. This is stimulating a search for other genes associated with risk of breast cancer, but it also means that, for now, many women in the sample will not receive testing. Some have already been sent a letter explaining the predicament of their families with respect to testing. These women will continue to be studied. Essentially they had met criteria for inclusion in the registry, and based on this, they were led to believe that genetic testing would be an option. They are not being told that they are not members of a hereditary breast and ovarian cancer family, only that the families are not characterized by a known mutation of BRCA1 or BRCA2. This outcome is worthy of investigation and may have attendant psychological distress and other untoward consequences associated with it. Fortunately, we have baseline assessments of these women and as noted above, we have instituted interim and follow-up assessments of them.

Women in the Hereditary Breast and Ovarian Cancer Registry are scattered across the country. In order to receive results, women who are not located in close proximity to the University of Pennsylvania, University of Michigan, or other select sites must identify a physician and through that physician, provide a clinical consent. Only then will results be released. Concerted efforts are being made nationally to increase the availability of individuals qualified for counseling, disclosure of results, and follow up. The shortage of such physicians and some difficulties in their understanding of the consent process led to some delays early in the project, but physician shortage is no longer a barrier to the release of test results. In fact, recognizing that alternative methods of delivering test results may be needed as demand for testing increases, we are designing a study specifically addressing the relative feasibility and effectiveness of telephone disclosure of test results by practitioners.

Measures

Our selection of measures meets or exceeds what was proposed in our original grant application. Copies of our battery of instruments are included as Appendix B. Table 1 lists the study's main measures for proband women and their husbands.

Table 1
Selected Assessment Measures

<u>PROBAND MEASURES</u>		
Questionnaire	Interview	Interim Assessment
Demographics	Contextual Rating of	HSCL-25, MOS-36
Health Locus of Control	Cancer Threat:	Cancer Worries
Risk Perception	Affected Relatives	FAD, Short-Form DAS
Intention to Seek Testing	Relationship to	Quality of Social Support
Knowledge, Beliefs and Attitudes	Proband	Life Cycle Issues
Reasons for Seeking Testing	Outcome	Receipt of Individual,
Cancer Worries	Involvement of	Group, & Family, Counseling & Education
Stressful Life Events	Proband In Care	COPE
Optimism (LOT)	Effects on Proband's	Relationship-Focused Coping
Miller Behavioral Styles Scale (MBSS)	Life	CBCL
Hopkins-25, MOS-36, AUDIT	SCID Depression, Anxiety, & Substance Use Modules	Evaluation of Preventive
Dyadic Adjustment (DAS)	Cancer-Specific Support Processes	Options
General Family Functioning (FAD)		
Social Support & Cancer-Related Support Processes		
<u>HUSBAND QUESTIONNAIRES</u>		
Demographics	COPE	Stressful Life Events
Health Locus of Control Risk	Knowledge, Beliefs and Attitudes	CBCL
Perception	Anticipated Reactions	LOT, MBSS, HSCL-25,
Worries About Wife's	Social Support & Cancer-Related	MOS-36
Risk of Cancer	Support Processes	AUDIT
Preference for Wife's Testing		DAS, FAD
Relationship-Focused Coping		

Sample

Table 2 presents basic demographic data on the proband women in this study. They are similar to other samples of persons seeking genetic services in that the majority are married, relatively well educated, and earning fairly high incomes.

Table 2
Basic Demographic Data

	<u>ALL WOMEN</u>	<u>UNAFFECTED WOMEN</u>	<u>AFFECTED WOMEN</u>
Age	48.52 (12.07)	46.15 (12.06)	51.58 (11.40)
Religion:			
Christian	72.5%	78%	69.6%
Marital Status:			
Married/with partner	81.4%	81.9%	85%
Number of Children	2.09 (1.38)	1.95 (1.39)	2.25 (1.35)
Education:			
At least some college	78.8%	81.8%	79.4%
Employed Outside Home	61.4%	64.5%	60.7%
Annual Household Income	\$50,000	\$50,000	\$50,000

During Year 4 of this study, an additional 25 women progressed from pre-results to post-results, yielding a total of 87. An additional 12 women have completed the first phone follow-up assessment (for a total of 45), and 4 have progressed to the second follow-up assessment (for a total of 37). Since the last annual report, 10 additional women have completed the final 12-month assessment, yielding a total of 26.

In addition to continuing to track the existing sample from pre-results through to follow-up, we have also worked to expand our baseline sample. As a result of an adjunct study with our collaborators at the Cancer Risk Evaluation Program (CREP), we have recruited about 100 new participants, including a small sample of male probands. We have begun to integrate these new participants into our established assessment schedule, and will randomize these participants to compare the efficacy of different methods of disclosing results.

Psychological Distress

This study included several measures of psychological distress, including the 25-item version of the Hopkins Symptom Checklist (HSCL-25), single items assessing cancer-specific worry and related functional impairment, and the intrusion subscale of the Impact of Events Scale (IES). The HSCL-25 (Derogatis et al., 1974) is highly correlated with the standard 58-item version (Heshbacher, Downing, & Stephansky, 1978), and has a better balance of sensitivity and specificity than a number of other screening instruments such as the CES-D (Heshbacher et al. 1978; Hough et al. 1982). There is extensive data using this scale with healthy, physically ill, and psychiatric samples (Cohen, Coyne, & Duvall, 1993; Coyne & Smith, 1991; Coyne & Sonnega, 1995, Pepper, Coyne & Cohen, 1996).

In previous years we have described results related to psychiatric morbidity and the performance of screening instruments in making accurate psychiatric diagnoses. In these initial analyses, the HSCL-25 served as the measure of distress and a telephone interview using modules of the SCID served as the measure of current and lifetime psychiatric morbidity. We found surprisingly low levels of psychological distress, and even lower levels of psychiatric disorder. In the second year, we modified our earlier results based on continued accrual of subjects, although the pattern of remarkably low distress and psychiatric morbidity remained. In general, both affected and unaffected in our sample are remarkably free of distress. Table 3 presents mean HSCL-25 scores and percentages of women meeting or exceeding the clinical cut-off for depressive symptomatology. Because there were no significant differences between affected and unaffected women, HSCL-25 scores are collapsed across the entire sample.

Table 3
HSCL-25 Psychological Distress

	BASE- LINE	INTERIM 1	INTERIM 2	PRE- RESULTS	POST- RESULTS 1	POST- RESULTS 2	POST- RESULTS 3
HSCL - 25	37.56 (9.15)	37.01 (9.04)	37.79 (9.21)	36.77 (9.71)	38.67 (11.46)	36.54 (9.03)	34.23 (9.07)
% Above Clinical Cutoff of 43	21.2%	20.2%	19.7%	14.4%	26.7%	13.5%	11.5%

The finding that about one-quarter of women met or exceeded the clinical cut-off led to two follow-up studies. The first involved a set of analyses assessing the performance of screening measures in predicting clinical disorder. Specifically, we compared rates of lifetime depressive disorder according to a diagnostic interview (SCID) with two self-report screening measures of history of depression. One measure was a simple self-report of history of 2-weeks mood disturbance with or without functional

impairment. The second self-report measure was the HSCL-25. The results of these analyses are reported in an article that is in press at the Journal of Psychological Assessment (Coyne, Thompson, & Racioppo, 2000).

According to the SCID interview, 66 (20%) of the women had a history of depression. The simple self-report concerning past two weeks mood disturbance yielded a much higher number of women reporting a history of depression (148, or 45%). Not only were the estimates of prevalence vastly different between semi-structured interview and simple self-report, but there was not significant overlap between semi-structured interview and simple self-report in terms of who had a history of depression and who did not, $\chi^2 (1, n = 323) = .51, n.s.$ The correspondence between self-report and structured interview of history of depression is shown in Table 4. It is noteworthy that only 48% of the women who had been found to have a history of depression in the interview reported a lifetime two weeks mood disturbance in the later self-report assessment. Specificity for the simple self-report was a modest 56.4 % and sensitivity was even worse (48.5 %). Positive predictive value was only 22.2%.

Table 4

Correspondence Between Self-Report and Structured Interview
of History of Depression.

Self-Reported Mood Disturbance	SCID-Diagnosed Lifetime MDD	
	No History	History
No History	112	32
History	145	34

Comparing SCID diagnosis with self-reported distress, women who reported a past episode of depression in the SCID interview were more likely to have been distressed according to a standard cut-score of 44 on the HSCL-25 than were women who did not report prior depression, $\chi^2 (1, n = 323) = 21.31, p < .001$. This relation held even when the few (2%) women were excluded who met criteria for current major depressive disorder, $\chi^2 (1, n = 317) = 16.13, p < .001$.

To examine the possibility that highly distressed women are sensitized to remember past episodes of depression, we examined the relationship between SCID-detected and self-report history of depression in women who had elevations above the cut-score on the HSCL-25. There was no significant relationship between SCID-detected and self-report history of depression in this group of women, $\chi^2(1, n=63) = 1.96$, n.s. Table 5 summarizes these values.

Table 5

Correspondence Between HSCL - 25 Distress and Structured Interview
of History of Depression

Self-Reported HSCL-25	SCID-Diagnosed Lifetime MDD	
	No History	History
Not Distressed	217	43
Distressed	50	23

In short, despite the finding that about one-quarter of women reported psychological distress above the accepted clinical cut-off, these scores were poor indicators of clinical disorder. The second follow-up study involves predicting clinical disorder, given that screening instruments are not efficient at doing so. Recently published studies suggest that depressive symptoms in response to stressful events (such as cancer or genetic testing for cancer) can be explained in large part by accounting for past history of depressive episodes (Maunsell, Brisson, & Deschenes, 1992; McDaniel, Musselman, & Nemeroff, 1997; Schover, 1991). Because so few participants met criteria for Current Major Depressive Disorder in this study, there is not enough power to test the hypothesis that past major depressive episode predicts future episodes with the current sample. However, this study provided pilot data that allowed us to apply for additional funding with several other granting agencies, and we anticipate a positive review of a grant specifically focused on testing past depression as a predictor of subsequent depressive episodes.

The Women's Health Study also included several items commonly used to assess breast-cancer specific distress among genetic testing participants. These common measures assess the degree to which participants worry about breast cancer, the degree to which these worries interfere with their daily lives, and distress in response to cancer- or risk-related events (i.e., being a member of a family with a cancer history, being offered genetic testing, and the possibility of being told that one is positive or negative for a genetic mutation). As Table 6 illustrates, while women report moderate levels of breast cancer worry on average, they report little to no functional impairment due to these worries.

Table 6
Cancer-Specific Worry

1= Not at All, 5= All the Time	BASE- LINE	INTERIM 1	INTERIM 2	PRE- RESULTS	POST- RESULTS 1	POST- RESULTS 2	POST- RESULTS 3
How often do you worry about developing breast cancer?	2.87 (.98)	2.74 (.99)	2.17 (1.02)	2.92 (1.20)	2.60 (1.16)	2.24 (.97)	2.54 (.90)
To what extent do these worries interfere with your every day life?	1.65 (.92)	1.47 (.76)	1.48 (.65)	1.77 (1.05)	1.36 (.77)	1.32 (.56)	1.31 (.68)

Often strong conclusions are drawn based on the responses to these items, relying solely on face validity because the concurrent or predictive validity of the items has not been established. Our study allows a test of the validity of these items by comparing these items to responses to standardized measures. Risk- and cancer-related distress was compared to self-reported psychological distress as measured by the HSCL-25. Interference due to worries was compared to several functioning sub-scales of the Medical Outcomes Study, Short Form-12 (Ware, Kosinski, & Keller, 1996). The results are reported in a manuscript submitted to an academic journal for review.

Chi-square analyses were used to determine the specificity and sensitivity of cancer-specific worry as a predictor of clinically significant levels of distress. Results show good sensitivity, with 81.6% of women who report lower levels of worry also reporting levels of distress below the clinical cutoff. However, self-reported worry had poor specificity in predicting distress, with 9.8% of women who

reported higher levels of worry also reporting clinically significant levels of distress (i.e., HSCL - 25 score of 44 or greater). Approximately one quarter of participants were misclassified as either false-positive (14.3%) or false-negative (12.5%). In addition, results also show that only 2.7% of women who report higher levels of worry also report levels of distress over one standard deviation above the mean on the SF-36 Mental Health subscale. Approximately 73% of women reporting lower levels of worry fall below that cutoff on the SF-36 Mental Health subscale. Nearly one quarter of women were misclassified as either false positive (21.4%) or false negative (2.7%). In short, high levels of risk- or cancer-related worry as assessed by commonly-used self-report items are not good indicators of clinically-significant distress or impairment.

The Intrusion sub-scale of the Impact of Events Scale (IES, Horowitz, Wilner, & Alvarez, 1979) was included in the 2-month post-results telephone assessment to indicate distress related to receiving genetic testing results. The IES is often used in cancer risk studies, with a wide range of mean scores. For instance, studies of participants in cancer risk-counseling (Lerman et al., 1995; Lloyd et al., 1996) find low rates of intrusive thoughts. Mean intrusive thought scores are slightly higher for the WHS sample, but still well-below the cut-point of 19 suggested by the developers of the scale. As Table 7 indicates, on the whole, it does not appear that receipt of test results leads to excessive cancer-specific worry.

Table 7
Cancer-Specific Worry

	<u>WHS 2-month Post- Results</u>	<u>Cancer Risk Counseling Participants (Lloyd et al., 1996)</u>	<u>Cancer Risk Counseling Participants (Lerman et al., 1995)</u>
IES Intrusive thoughts			
Mean	11.82	6.9	3.6 & 7.5
(SD)	(13.06)	(7.4)	(4.6 & 6.9)

Interest in Obtaining Testing

Table 8 presents data concerning the intention to receive testing when it is offered. As can be seen, the majority of women expressed an interest in obtaining results when assessed at baseline.

Table 8

Intention To Receive Test Results

	<u>TOTAL SAMPLE</u>
Definitely Will Receive Results	68.3%
Probably Will Receive Results	20.0%
Undecided	7.5%
Probably or Definitely Will Not Receive Results	4.1%

Now that test results have been made available to much of the sample, we are able to assess the degree to which intentions to pursue testing expressed at baseline predict actual receipt of results. A t-test found that women who actually received results as of Year 4 of the study were significantly more likely to report intentions to receive results than women who did not receive their test results ($t = -2.33$, $p = .02$). However, expressing the intention to get test results did not significantly predict actual receipt of test results. Collapsing across the “definitely” and “probably” responses at each end of the intention continuum, and excluding the ambiguous “undecided” response, a crosstabs calculation yielded a positive predictive value (PPV) of 12%, and a negative predictive value (NPV) of 95%. These results mean that if a woman expressed the intention to get test results, only 12% of the time did she actually receive results by Year 4, and that if a woman expressed the intention not to get results, it is very likely that she did not receive results by Year 4. However, given that most women expressed the intention to receive results, and relatively few women actually did receive results, it is unlikely that intention to get test results would predict actual receipt of results with any accuracy.

Table 9 provides data concerning the women’s reasons for obtaining test results. It appears that women with and without a personal history of cancer diagnosis seek genetic testing for different reasons than women with a personal history of cancer. Women without a personal history of cancer are significantly more likely than affected women to seek testing for most reasons, including those related to planning for the future, modifying screening behavior, and reducing uncertainty. While both affected and unaffected women reported seeking testing to clarify their children’s cancer risk, women with a personal history of cancer were significantly more likely to be motivated by this factor. This result is consistent with our anticipation of the salience of such family issues in the reasons for undergoing testing. Moreover, now that it has been decided that testing is appropriate for unaffected women only when they are members of families with known mutations, the saliency of family issues for affected women is likely to increase.

Table 9
Reasons For Seeking Testing

	<u>ALL WOMEN</u>	<u>UNAFFECTED WOMEN</u>	<u>AFFECTED WOMEN</u>
To Plan for Future	38%	50.96%	24.8%***
To Reduce Uncertainty	53.5	66.4	40.7***
To Be More Careful About BSE	30.8	40.9	20.1***
To Decide About Prophylactic Surgery	37.4	47.5	27.1***
To Decide About Family Planning	6.4	9.3	3.3**
To Assess Risk To Children	54.3	45.2	68.2***
Family Urges Testing	11.4	11.2	12.1

*p < .05 **p < .01 ***p < .001

Perceived Risk of Breast Cancer

Table 10 summarizes women's perceived risk of breast cancer assessed at baseline and again 6 months after results-disclosure. Consistent with findings from other registry samples (Lerman, Kash, & Stefanek, 1994), women in this sample perceived their risk for breast cancer as fairly high, averaging about 50% lifetime risk. We compared women's subjective risk perception with objective risk estimates derived from the Claus model (Claus et al, 1994), which predicts lifetime risk by accounting for cancer occurrence and age of onset in first-degree and second-degree relatives. Claus estimates are only estimated for unaffected women, because lifetime risk estimates among women with a personal history of cancer are not meaningful. On average, women significantly overestimated their perceived risk of cancer relative to objective Claus risk estimates, which averaged 22.55 (SD = 10.77), and ranged from 8.30 to 48.40.

At baseline, women with a personal history of cancer perceived themselves as significantly less likely to get cancer than unaffected women, both in the near future and over their lifetimes. When assessed again at 6 months after receiving test results, affected women perceived their risk of developing cancer in the near future as greater than they previously had. Because of the relatively small sample at post-results, the increase in risk perception was significant only for affected women's perception of lifetime risk (36.2% vs. 56.2%). Also, unaffected women's perception of cancer risk seemed to decrease over time, while affected

women's perception of risk increased over time, although these differences were non-significant with the current small sample. As more women reach the follow-up assessment, we will have the statistical power necessary to test for significant differences, and to determine whether this finding has meaningful implications for high-risk testing and counseling.

Table 10
Perceived Likelihood Of Breast Cancer Among Women in the Research Registry

	Baseline		
	All Women	Unaffected Women	Affected Women
In the Near Future	36.4%	44.2%***	26.5%***
In Lifetime	50.9%	62.7%***	36.2%*** _a
	6 Months Post-Results		
	All Women	Unaffected Women	Affected Women
In the Near Future	38.8%	30.8%	46.2%
In Lifetime	47.2%	37.5%	56.2% _a

*** $p < .001$;

Values with same subscript are significantly different at $p = .02$

Our closer proximity to the CREP group at the University of Pennsylvania has offered the opportunity to compare our research sample to a large sample of high-risk women seeking cancer risk counseling through the CREP clinic. A collaborative manuscript recently submitted to Cancer Epidemiology, Biomarkers, and Prevention described risk perception among this large clinic sample. Similar to the research sample, women in the clinic sample largely overestimated their lifetime numeric risk, averaging 49.1% (SD = 32.7). A paired t-test yielded a significant difference between objective risk estimates ($\bar{X} = 26.0\%$, SD = 17.4) and numeric risk perception ($t = -8.07$, $p < .00$).

Additionally, we investigated the relationship between risk perception and distress among both the research and clinic samples. Among the research sample, correlations between perceived risk of developing breast cancer and HSCL-25 psychological distress were modest but significant ($r = .12$, $p < .05$, for lifetime

risk). Similarly, among the clinic sample, correlations between breast-cancer specific worry (as assessed by the Impact of Events Scale, Horowitz, Wilner, & Alvarez, 1979) and risk perception were modest but significant ($r = .26, p < .00$). These results are especially important because the current literature assumes that overestimation of cancer risk signals risk for psychological distress, and that accurate numeric risk information is an antidote for apparent catastrophizing about breast cancer risk. However, despite the large overestimates of numeric risk reported by women in both the research and clinic samples, women did not report high levels of psychological distress, and distress was only moderately related to measures of risk perception.

Post-Traumatic Growth

In addition to the many challenges that cancer risk presents to a woman and her family, clinicians and researchers find that some women find unexpected benefits in potentially-traumatic experiences. Affleck and Tennen (1996) describe a construct called "benefit-finding", defined as a "search for uplifting meaning from threatening experiences," or said another way, finding the positive in largely-negative events. They report that subjects with widely varying medical problems report finding benefits, including the strengthening of relationships, positive personality change, and the re-ordering of life priorities and goals. Referring specifically to cancer patients, Seligman (1996) observes, "People who cope with cancer and survive seem to develop new strengths and perspectives...[those] who successfully pass through the crisis phase of cancer have faced danger and decisions but also have the opportunity for change and growth" (pp. 268-269). Simonton, Matthews-Simonton, and Creighton (1992) describe this phenomenon among cancer patients, asserting that "the recovered patient is weller than well" (p. 77). It may be that the experience of being a member of a high-risk family and getting genetic testing for cancer risk is a catalyst for positive change.

The present study tested this hypothesis by assessing post-traumatic growth (i.e., positive changes in response to being at high risk for cancer (before receiving test results) and to receiving test results after results-disclosure. This study utilized a 14-item measure of post-traumatic growth developed by Tedeschi and Calhoun (1996), with a maximum score of 84. As shown in Table 11, when collapsing across breast cancer status, women report fairly high and stable levels of post-traumatic growth for two annual interim assessments and then again before receiving results. After results-disclosure, however, reported post-traumatic growth appears to decrease dramatically, although this difference is not significant likely due to the small sample size. Next, analyses compared post-traumatic growth reported by women with and without a personal history of breast cancer. At the second interim assessment, affected women reported significantly more post-traumatic growth in response to being at high risk for cancer than did unaffected women. Also, among affected women, post-traumatic growth from receiving genetic testing results was significantly lower than post-traumatic growth from being at high risk for cancer. Although preliminary due to the small sample sizes at follow-up, these results suggest that affected and unaffected women construe testing differently, and

that it may impact their lives in different ways. As we accrue more follow-up data, we will explore this possible explanation further.

Table 11
Post-Traumatic Growth by Time of Assessment and Breast Cancer Status

Breast Cancer Status	INTERIM 1 (N = 329)	INTERIM 2 (N = 153)	PRE- RESULTS (N = 114)	POST- RESULTS 2 (N = 25)
All Women	58.89 (15.36)	60.16 (16.03)	61.33 (15.34)	44.80 (22.18)
Unaffected	59.03 (16.12)	57.47 _a (16.34)	58.67 (18.30)	55.50 (22.75)
Affected	59.05 (14.56)	64.33 _a (14.71)	62.19 _b (14.87)	37.88 _b (21.31)

Values with the same subscript are significantly different at $p < .01$

Husband Functioning

Table 12 summarizes husband's reports of functioning at baseline assessment and at approximately 8 months after their wife-probands received genetic test results. Because of small sample sizes for follow-up, comparisons between time points should be considered tentative, but we anticipate a significant increase in husband follow-up assessments as the number of women seeking testing increases with the release of a large number of test results. Recognizing their limitations, this initial data seems to suggest that husbands report fairly low and stable levels of psychological distress and worry related to their wives developing breast cancer. Husbands' perceptions of their wives' lifetime risk of breast cancer appear to decrease after testing, although it remains to be seen whether this decrease is statistically significant, or perhaps more importantly, whether it is clinically significant.

Table 12
Husband Functioning at Baseline and Follow-up Assessments

	Baseline (n=226)	8-Month Follow-Up (n=14)
Psychological Distress (HSCL - 25)	34.74 (7.94)	38.08 (7.85)
Worry about Wife Developing Breast Cancer (1= Not at all, 5= All the time)	2.85 (1.17)	2.23 (1.01)
Interference from Breast Cancer Worries (1= Not at all, 5= All the time)	1.78 (.91)	1.38 (.77)
Perceived Short-Term Risk of Wife Developing Breast Cancer	23.80% (24.00)	26.92% (19.32)
Perceived Lifetime Risk of Wife Developing Breast Cancer	36.62% (28.65)	29.23% (20.60)

Husbands also responded to questions about discussions with their wives about cancer risk and genetic testing. On average, husbands reported that their wives rarely seek support from them regarding cancer risk, and that husbands feel that this poses very little burden. Husbands also report the frequency with which they discuss genetic testing with their wives ranges from sometimes to often. Over half of husbands report that their wives initiate these discussions, while about a quarter of husbands report that they and their wives initiate these discussions equally often, and about one-fifth report that they themselves initiate these discussions.

Couple Functioning

The literature addressing couples managing chronic or serious illness often concludes that couples function as a unit, sharing attitudes about risk, being equally distressed and impaired by illness, and being equally involved in preventive and treatment decisions and procedures. One problem with this literature, though, is that most studies of couples facing illness have traditionally focused on male patients and their wives. The Women's Health Study presents a unique opportunity to test the process of couples coping with illness when the wife is the identified patient or proband. Given the findings of the general marital literature,

including sex differences in coping, the experience of affect, and approach to problem-solving, it may be that female patients and their husbands respond to illness differently than male patients and their wives.

To explore these questions, we compared women-probands' risk perception, psychological distress, risk-related impairment, and involvement in risk-related activities to those of their husbands. Table 13 summarizes these comparisons, showing that there were no significant correlations between female participants' responses to genetic testing and their husbands' responses. Further, husbands reported significantly less psychological distress, and lower perception of wife's risk of breast cancer than did women participants. Also, there was a trend toward husbands reporting more functional impairment due to breast cancer worries than did their wife-participants. These data suggest that couples in which the female is the identified participant may manage illness-related events differently than couples in which the male is the identified participant.

Table 13
Responses to Testing of Proband-Women and their Husbands

	Proband Women	Husbands	p of difference	r
Psychological Distress (HSCL - 25)	37.21 (8.88)	34.83 (8.06)	.003	.13
Worry about Developing Breast Cancer (1= Not at all, 5= All the time)	2.81 (1.01)	2.89 (1.13)	ns	-.00
Interference from Breast Cancer Worries (1= Not at all, 5= All the time)	1.68 (.96)	1.91 (1.02)	.07	-.02
Perceived Lifetime Risk of (Wife) Developing Breast Cancer (0 – 100%)	47.75% (31.60)	36.95% (29.45)	.00	.11

Sister Functioning

Women participating as probands in the Women's Health Study were asked to consider giving consent for us to contact their sisters, both before and after results-disclosure. Table 14 summarizes several key aspects of sister functioning. At both assessment points, sisters reported relatively low levels of psychological distress. Before results-disclosure, only 8.6% of sisters reported distress exceeding the standard cut-off of 43 on the HSCL-25. After results-disclosure, only 6.7% exceeded the standard cut-off. Sisters also saw themselves at high risk, breast cancer-specific worries, and interference from worries

Table 14
Sister Functioning at Baseline and Follow-up Assessments

	Baseline	8-Month Follow-Up
Psychological Distress (HSCL - 25)	36.14 (10.35)	37.00 (6.00)
Worry about Developing Breast Cancer (1= Not at all, 5= All the time)	2.74 (1.11)	2.47 (1.25)
Interference from Breast Cancer Worries (1= Not at all, 5= All the time)	1.35 (.69)	1.40 (.63)
Perceived Risk of Developing Breast Cancer Relative to the Average Woman (1= Much lower, 5= Much higher)	3.79 (1.24)	-----

On average, sisters reported that their proband-sisters sometimes seek support from them regarding cancer risk, and that sisters feel that this poses very little burden. Sisters also report that they discuss genetic testing with their proband-sisters sometimes, and that these discussions are somewhat satisfying. Over two-thirds of sisters report that they and their proband-sisters initiate these discussions equally often, while one-fifth report that their proband-sister initiates discussions.

Social Support

In addition to assessing the functioning of husbands and sisters of proband women, we also asked probands themselves about their social relationships and the degree to which friends and family are involved in the process. Overall, probands rated spouses as most important and involved in the process. Table 15 summarizes these results.

Table 15
Family Involvement in Genetic Testing

1 = Not at all	2 = A little	3 = Somewhat	4 = A great deal	
Question	Spouse	Mother	Sister	Daughter
1. How often do you discuss your risk for breast cancer/living with breast cancer with your ____?	2.85	2.43	2.58	1.71
2. How satisfied are you with these discussions?	3.23	3.05	3.18	---
3. Overall, how important is your ____'s opinion in your decision whether or not to be tested for the breast cancer gene?	2.80	2.29	2.37	2.38
4. In making decisions about what to do to reduce your risk of breast cancer in the future, how important is your ____'s opinion?	3.02	2.47	2.47	2.53

Additionally, probands described who initiates discussions of cancer risk. As seen in Table 16, the majority of probands report that they themselves initiate discussions about risk with their husbands. This is consistent with husbands' own reports of risk discussions with their proband-wives. About half of probands report that they initiate discussions with their mothers, and about one-fifth report that mothers initiate risk discussions. Similarly, a little less than half of probands initiate risk discussions with sisters, and a little less than half of probands report that they and sisters initiate discussions equally. This contrasts with sisters' own reports, where over two-thirds said that they and their proband-sisters initiate discussions equally often.

Table 16
Initiation of Discussions of Cancer Risk

		Percentage of Time Each Party Initiates Discussions of Cancer Risk?		
Specific Other		Proband	Other	Equally
	Spouse	79.4	4.1	16.5
	Mother	53.8	21.8	24.4
	Sister	42.8	15.5	41.7

Interim Assessments

In response to delays between baseline assessment and actual receipt of test results, we added a yearly interim assessment to our already comprehensive schedule of follow-ups. In this fourth year of the project, we completed another interim assessment for women who had not yet received their test results. The main purpose of the interim assessment was to continue to monitor women's experiences with the genetic testing process, and to ensure that we had up-to-date measures of areas of functioning that might change over time (i.e., states rather than traits). Additionally, the interim assessments allow us to test hypotheses regarding causal relationships between variables, instead of relying on inferences from concurrently-collected data. Finally, these repeated measures allow us to explore psychometric issues, such as the stability and reliability of constructs and measures over time.

Like the investigator team, many women who joined the cancer registry, and specifically this study of the genetic testing process, did not anticipate that the process would take so long. One important question addressed by the interim data is the psychological impact this delay in testing has had on women. Table 17 compares key indicators of functioning of proband women annually from baseline to the second interim assessment. Of particular interest are the findings that the delay in testing does not appear related to increased psychological distress, so that a long delay between the possibility of testing and availability of results does not appear to lock women in a long-term stressful experience. Also, intention for testing is fairly stable over the waiting period, suggesting that women did not appear to get discouraged from testing because of unexpected delays in the availability of results. Finally, women's reports of optimism increased significantly from baseline to interim assessment.

Table 17
Functioning at Baseline and 2 Yearly Interim Assessments

	Baseline	Interim 1	Interim 2
Psychological Distress (HSCL-25)	37.56 (9.15)	37.01 (9.04)	37.79 (9.21)
Breast Cancer Worry (1= Not at all, 5= All the time)	2.87 (.98)	2.74 (.99)	2.17 (1.02)
Interference from Worry (1= Not at all, 5= All the time)	1.65 (.92)	1.47 (.76)	1.48 (.65)
Intention for Seeking Testing (3= Definitely, 2= Probably, 1= Undecided, 0= Definitely not)	2.53 (.80)	2.37 (.84)	2.20 (.99)
Importance of Health (Range 4 – 20)	14.60 (3.52)	14.95 (3.31)	13.92 (4.41)
Life Events (Number of life events)	1.01 (1.21)	.82 (1.09)	.89 (1.05)
Optimism (Life Orientation Test)	29.79 (5.83)	42.87 (9.64)	43.62 (8.96)

Impact of Genetic Testing

As more women are being offered test results, we are beginning to accrue more follow-up data describing women's experiences with genetic testing. As shown in Table 18, women rated the impact of testing on their lives, including their work and family lives, as largely positive. The impact of testing on women's work was significantly less positive than its impact on other areas of their lives.

Table 18
Impact of Genetic Testing at 6-Month Follow-up (Interview)

1= Very negative effect, 3= No effect, 5= Very positive effect	All Women (n = 35)	Uninformative Results (n = 28)	Negative for known mutation (n = 1)	Positive for known mutation (n = 7)
Effect of testing on your family	3.43 (.69)	3.50 (.64)	4.00 (.00)	3.43 (.79)
Effect of testing on your work	3.05 ^a (.40)	3.07 (.38)	3.00 (.00)	3.14 (.38)
Effect of testing on your concerns for child's future	3.45 (1.06)	3.54 (1.07)	2.00 (.00)	3.33 (1.03)
Overall effect of testing on your life	3.54 (.69)	3.57 (.63)	4.00 (.00)	3.57 (.98)

^a Significantly different from other areas at $p < .05$.

Additionally, women described their psychological distress at two time points after results-disclosure, and the degree to which they regret participating in genetic testing (see Table 19). Women report little distress in response to receiving test results, and report little regret for participating in testing. Notably, women receiving uninformative results appear to report the highest levels of distress and regret, although small sample sizes make statistical comparisons inconclusive at this time.

Table 19
Responses to Genetic Testing at 6-Month and 12-Month Follow-ups (Questionnaire)

6-Month Follow-Up				
	All Women (n = 26)	Uninformative Results (n = 20)	Negative for known mutation (n = 2)	Positive for known mutation (n = 4)
Distress Upon Receiving Results (1= Not at all, 5= Very distressed)	2.08 (.41)	2.25 (.48)	1.5 (.71)	1.25 (.25)
Regret Decision to Be Tested (1= Not at all, 5 = Very much so)	1.29 (.86)	1.35 (.93)	1.00 (.00)	1.00 (.00)
12-Month Follow-Up				
	All Women (n = 25)	Uninformative Results (n = 21)	Negative for known mutation (n = 2)	Positive for known mutation (n = 4)
Distress Upon Receiving Results (1= Not at all, 5= Very distressed)	1.88 (1.33)	1.90 (1.41)	1.00 (.00)	1.75 (.96)
Regret Decision to Be Tested (1= Not at all, 5 = Very much so)	1.16 (.62)	1.19 (.68)	1.00 (.00)	1.00 (.00)

Key Research Accomplishments

As of this report, our research has yielded a number of interesting findings, including:

- ♦ Women from registry samples participating in genetic testing appear to have higher incomes, more education, and more stable marriages than the general population.
- ♦ Participants in genetic testing for cancer risk appear to have low levels of psychiatric morbidity or clinical disorder.
- ♦ Psychological distress is not a useful predictor of clinical disorder.
- ♦ Retrospective reports of depressive episodes more accurately reflect current mood than history of depressive episodes.
- ♦ Women participating in genetic testing for cancer risk tend to greatly overestimate their breast cancer risk.
- ♦ Overestimates of cancer risk are not highly related to psychological distress.
- ♦ Different ways of assessing risk perception yield different responses, although these responses are all equally correlated with distress.
- ♦ Common ways of assessing breast cancer worry are not highly related to standard measures of clinical disorder, functional impairment, or psychological distress.
- ♦ Women with and without a personal history of breast cancer have different motivations for pursuing genetic testing.
- ♦ Women with and without a personal history of breast cancer are differentially affected by the process of genetic testing.

Reportable Outcomes

The following manuscripts have been published, or submitted for publication, based on data from the current study:

Coyne, J.C., Thompson, R., & Racioppo, M. W. (2000). Validity and efficiency of screening for history of depression by self-report.

Kruus, L. K., Racioppo, M. W., & Coyne, J. C. (submitted for presentation). Distress in anticipation of BRCA 1/2 testing: Some relevant comparisons. Enhancing Outcomes in Women's Health, conference to be held in October, 2001.

Racioppo, M. W., Armstrong, K., Weber, B., & Coyne, J. C. (submitted for publication). Comparison of numeric, qualitative, and comparative measures of breast cancer risk perception. Cancer Epidemiology, Prevention, and Biostatistics.

Racioppo, M. W., Armstrong, K., Kruus, L. K., & Coyne, J. C. (2000). Understanding risk perception among women attending the cancer risk evaluation program. Paper presented at the Irving and Eunice Leopold Research Symposium, University of Pennsylvania.

Racioppo, M.W., & Coyne, J. C. (submitted for presentation). Husbands of women anticipating genetic testing for risk of breast cancer. Enhancing Outcomes in Women's Health, conference to be held in October, 2001.

CONCLUSIONS

While analyses are ongoing, both in terms of describing baseline functioning and in predicting follow-up functioning, some initial conclusions can be drawn from analyses completed to date. One important conclusion is that, at least among this group of self-selected women, reports of extreme psychological distress and, especially, psychiatric diagnoses, were rare. At their baseline assessment prior to being offered genetic testing, both women affected and unaffected by breast cancer were remarkably free of psychological distress and psychiatric morbidity. Despite their increased risk for breast and ovarian cancers, as well as their repeated exposure to breast cancer personally or through their relatives, they appeared resilient in the face of the potentially stressful experience of genetic testing. Our findings have a number of implications. Most importantly, it appears that when women approach the process of counseling, education, and decision making about testing, they will not be impaired by their pre-existing psychological state. That is not to say that the actual experience of counseling, having to make a decision about testing, or the receipt of positive results will not engender distress. However, the assumption that these women will approach the process of genetic testing with distress and psychiatric morbidity was not substantiated by our findings. Rather, the results suggest that any substantial elevations of distress and psychiatric morbidity following the counseling process are best attributed to that process and not to the preexisting state of the women. It follows that efforts to manage psychological distress and the education and consent process should focus on acute needs, rather than be based on the assumption of chronic psychological problems.

Further, preliminary analyses of responses of women who have completed assessments through 12-month follow-ups suggest this pattern of resiliency and little distress persists over time. Looking at changes in psychological distress through the course of the genetic testing process, it appears that there may be a slight increase in reported distress during the few months after receiving test results, but that this increase does not reach clinical levels of symptomatology, and resolves to levels below those reported by women at baseline assessment. These same patterns were found for cancer-specific worry, and for interference in daily functioning due to cancer worry.

These distress findings have a number of implications that go beyond the question of determining the psychological state of women seeking predictive testing for risk of breast cancer. We have demonstrated that long-term survivors of cancer can be relatively free of psychological distress and psychiatric morbidity. Even though over half our sample were survivors of breast cancer, and had a greater lifetime incidence of depression than the unaffected women, these women were well within the expected prevalence for a representative sample of community-residing women. The low levels of distress and morbidity reported in this study suggest that previous findings of elevated distress may be confined to early adjustment to a diagnosis of cancer, or to the advanced stages of the disease. Our findings add to accumulating evidence that cancer does not necessarily result in psychiatric morbidity. We believe that attention can be more

productively directed at better understanding why these women defy the not unreasonable assumption that they are a distressed, depressed, and anxious group. The experience of living with familial risk of cancer may well have had a resiliency-building effect that more than cancels any vulnerability associated with it. The particular aspects of this experience, that cultivates resiliency and vulnerability, need to be specified. As others have noted, adversity can produce resiliency as well as vulnerability, and women anticipating testing provide an excellent opportunity to study this (e.g., Schaeffer & Moos, 1992).

An alternative explanation for the relative lack of distress reported by women in this sample is that the cancer registry draws a highly selective group of women. We certainly found that our sample is unusually stable - psychologically, financially, and maritally. We remain concerned about the generalizability of our findings, and those of other investigations of high-risk women drawn from registry samples. Members of high-risk families jointly participate in these registries, and they typically have marshaled considerable social support to manage their shared sense of being at high risk for cancer. Participation in these registries has also given these women exceptional opportunities to become informed about their risk of cancer and genetic testing, to come to terms with their risk status, and to evaluate the advantages and disadvantages of testing for themselves and their families.

In contrast, women from the community seeking testing are likely to be less socially advantaged, and less informed about, or are psychologically ill-prepared for, the dilemma of whether to proceed with testing. For these women, the decision to pursue testing may be precipitous and tied to recent stressors, such as positive mammography findings, or the diagnosis or death of a family member. Pre-existing psychological distress may impair these women's efforts to become educated about, and to decide on, the merits of testing for them. They may be naive about the potentially negative insurance issues and social discrimination associated with being known to have an altered gene. Social support related to being at high risk and to deciding about testing may be deficient or absent. Without appropriate services these women may obtain testing without giving adequate informed consent, which may have negative psychosocial consequences rather than the intended benefits of testing. Yet, at the present time, we lack the knowledge needed to specify just what services are appropriate. To address this lack of knowledge, we have begun studying women seeking assistance in evaluating and managing their cancer risk through the Cancer Risk Evaluation Program at the University of Pennsylvania Cancer Center. The intent of this work is to identify selection biases and discrepancies in experiences of registry and community women, data that will have direct and immediate application in the refining and evaluating of urgently needed clinical protocols.

Our thorough assessments also allowed us to evaluate the psychometrics of assessing important constructs such as psychological distress and risk perception. Our analyses found that self-reports of history of depression are greatly influenced by present mood, suggesting that researchers should not rely solely on such screening questions to assess depression history. Also, our psychometric study of risk perception among high-risk women suggests that there may be a disconnect between how researchers and participants

view risk. Both findings have implications for assessing and predicting response to genetic testing, and for how providers might intervene, or decide not to intervene.

In addition to clarifying distress and characteristics unique to our sample, we also uncovered interesting differences between women with a personal history of cancer, and those without, in terms of perceived risk of breast cancer, and motivation and intention to seek testing. For instance, women with a personal history of breast cancer perceived their short-term and lifetime risks of breast cancer as significantly lower than women without a personal history. Further analyses will explore possible explanations for this finding, including the degree to which it can be explained by a sense that one cancer event may protect against future events, that affected women perhaps feel more confident in their screening plan, or that past treatments, such as mastectomy, confer a lower sense of risk. Also, affected women were significantly more likely than other women to report they intend to seek testing immediately after it becomes available, and to pursue testing in order to clarify their children's risk of cancer.

Also regarding women's perceptions of breast cancer risk, all women overestimated their lifetime risk of breast cancer relative to objective risk estimates. It may be that psychosocial factors such as salient experiences with family members affected by cancer, or frequent focus on cancer and health may influence risk perception beyond objective information. Interestingly, women with and without a personal history of cancer reported different levels of risk perception at baseline, and different patterns of change from baseline to post-results follow-up. At baseline, affected women reported significantly lower risk perception than did unaffected women. However, at follow-up, affected women reported significantly higher risk perception than did unaffected women.

Another interesting finding relates to how women with and without a personal history of cancer make meaning out of their experiences with genetic testing. Specifically, unaffected women reported higher levels of post-traumatic growth regarding testing than did affected women. One possible explanation is that the experience of cancer re-calibrates a woman's sense of the meaning of stress, so that genetic testing becomes less of a traumatic event when one has already had cancer. These results corroborate the findings that affected and unaffected women experience genetic testing differently, and suggest that the needs of women regarding genetic testing may depend upon their personal cancer history.

In conclusion, our project continues to make substantial progress in data collection, analysis, and publication, and in establishing opportunities for collaboration and expansion of the current study. Such collaborations maximize the utility of the data already collected, and help us more easily to overcome a variety of methodological and logistical challenges. The excellent mental health of these women shifted the focus of our research from efforts to predict baseline vulnerability to an attempt to understand their resiliency in the face of their risk for breast cancer, to evaluate the stability of resiliency over time, and to investigate the role of assessment and research methodology in our results. As a byproduct of this effort, we produced data, from our affected women, that are optimistic concerning the mental health of longer-term cancer survivors.

In our fourth year, we continued with data collection, analyses, and dissemination, and have successfully expanded both our sample size and our research foci. In manuscripts and presentations to date, we have described the psychological functioning of women in the registry sample, both at baseline assessment and at time points along the process of genetic testing, and are able to state with some authority that women in this registry sample managed well the process of genetic testing. We have begun to compare women in the registry with women seeking clinical risk-management, and have found similarly low levels of distress and functional impairment in both samples. We have challenged the utility of the use of screening questions as indicators of clinically-relevant distress, and have highlighted the complexity of risk perception. We also described the social support processes among high-risk women in the cancer registry, including the degree to which husbands of women-participants are adversely affected by cancer risk and genetic testing. We have begun to explore explanations for observed differences between affected and unaffected women, regarding intention and motivation for testing, and risk perception before and after testing.

In our fifth year, we intend to continue to follow women through the process of being offered results, receiving results, and adapting to these results over the long term. We will continue collaborative studies discussed earlier, and will continue to develop opportunities for further collaboration to maximize the utility of data from the present study. We also plan to address the issue of selection bias in our registry sample, both by expanding our sample to include women with different socioeconomic backgrounds and different motivations for contacting the health system, and by thorough assessment of women who choose not to pursue results-disclosure. Finally, as more women progress to long-term follow-up, we plan to conduct analyses clarifying relationships between different aspects of women's experiences, taking full advantage of the longitudinal nature of this study and the unique opportunities this affords for causal modeling.

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APPENDIX A

Copies of Manuscripts and Presentation Abstracts

RUNNING TITLE: Numeric, qualitative, and comparative risk perception

Comparison of numeric, qualitative, and comparative measures of breast cancer risk perception.

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ABSTRACT

Perception of breast cancer risk is thought to be an important determinant of health-care decision-making, screening behavior, and psychological distress among women with family histories of breast cancer. Cancer risk counseling aims to assist women in accurately estimating their risk. Published guidelines currently suggest that cancer risk counseling convey numeric estimates of risk rather than ambiguous qualitative estimates, although women seem to be more accurate in estimating their qualitative risk than their numeric risk. The current study investigated the relative accuracy of numeric, qualitative, and comparative risk estimates, and the relationship of these estimates to cancer-specific distress. Women attending a high-risk cancer clinic (n=248) completed mailed surveys after receiving cancer risk counseling. Surveys assessed breast cancer risk perception as a percentage (numeric), as a Likert-type scale from low to high (qualitative), and compared to the average woman (comparative), as well as distress assessed by the IES, and other health services issues. Women significantly overestimated their numeric risk relative to objective risk estimates, but did not appear to overestimate greatly their qualitative or comparative risk. Additionally, on average women reported moderate levels of cancer-specific distress, and all three measures of risk perception were equally related to distress. Taken together, these results suggest that cancer risk counselors may be mistaken in relying solely on numeric risk estimates for conveying risk or assessing risk perception, and that overestimation of numeric risk does not necessarily indicate debilitating psychological distress.

INTRODUCTION

Risk perception figures heavily in the cancer risk counseling of women with family histories of cancer, and in the assessment of counseling effectiveness. Accuracy in a woman's perception of breast cancer risk is considered an important aspect of informed decision-making, a determining factor for screening behavior, and an antidote for excessive psychological distress¹. Additionally, the accuracy of participants' estimates of their risk of developing cancer obtained after counseling is often used as an indicator of counseling effectiveness.

The two most common methods of estimating objective breast cancer risk are models developed by Gail² and Claus³ both of which express risk in terms of a numeric probability or percentage. Published guidelines for genetic counselors emphasize the importance of communicating numeric risk⁴, and caution against the use of qualitative estimates of risk that might impose the counselor's values or otherwise violate a participant's self-determination^{5,6}.

The assumption underlying the use of numerical probability estimates is that counseling participants understand probability estimates, and that these provide a value-neutral scaling system for communicating risk. However, there is ample evidence that many people have difficulty interpreting quantitative data such as probabilities, which requires a cognitive ability termed "numeracy". For example, one study of women with a family history of breast cancer found that over 90% of women overestimated their numeric risk of developing breast cancer relative to objective Gail estimates, and that 66% of these women "extremely overestimated"

their risk⁷. A study by Schwartz⁸ found that a sample of female veterans performed poorly on numeracy tasks, and that the majority of women were unable to interpret numerical data about the reduction in risk of breast cancer death associated with use of mammography. Women with higher numeracy scores more accurately estimated the average risk of dying from breast cancer, and were better able to interpret numerical data about risk reduction. Another community study⁹ and a review by Woloshin et al.¹ report similar findings regarding poor numeracy, and the association between numeracy and accuracy of risk perception.

An alternative to numeric estimates of risk are qualitative measures, such as one's risk relative to the average woman, or one's risk on a continuum from low to high. Although the prevailing philosophy in cancer risk and genetic counseling has been to avoid such qualitative estimates of risk, such conceptions of risk may be important in participants' comprehension of risk. For instance, the finding that participants in cancer risk counseling have difficulty interpreting numeric probabilities, even after counseling that provides accurate risk estimates^{7,10}, suggests that risk is not simply a numeric construct for participants. Additionally, in comparing studies employing numeric or qualitative measures of risk perception, Woloshin, et al.¹ concluded that respondents were more accurate in estimating qualitative risk than they were in estimating quantitative risk.

The present study examined the concordance of numeric risk estimates to qualitative and comparative estimates among women who had received counseling concerning their personal

risk of breast cancer. A high concordance among these measures would suggest that different ways of assessing risk tap into a common risk perception construct. This study also compared numeric risk estimates to objective calculations of risk provided in counseling, and compared the relative accuracy of numeric, qualitative, and comparative risk estimates. Based on the results of previous research, we expected that numeric risk estimates would be overestimates relative to objective risk estimates. Finally, this study examined the degree to which different measures of risk perception were related to breast cancer-specific distress, one indicator of the utility of a particular measure of risk perception.

METHOD

Participants

A total of 248 women attending the Cancer Risk Evaluation Clinic for assistance in evaluating and managing their cancer risk participated in the present study. The average age of participants was 53 years ($SD = 10.58$), ranging from 21 to 88 years. Most participants were married (81.2%), Caucasian (71.7%), and college-educated (72.1%). About one-third had a personal history of breast cancer (27.9%).

Measures

Risk perception. Women were asked to estimate their chances of developing breast cancer at some point in their lifetime using three different measures: 1) a visual analog scale ranging from 0 to 100% chance of developing breast cancer (numeric); 2) a 5-point Likert-type

scale ranging from very low to very high chance (qualitative); and 3) a 5-point Likert-type scale ranging from much lower to much higher chance compared to the average woman (comparative). These represent the most common types of risk assessments used in previous studies¹.

Objective risk. Estimates of objective risk were calculated from participants' pedigrees collected as part of standard clinic practice, and based on the Gail, et al model². Gail risk estimates take into account the number of first- and second-degree relatives affected with breast cancer, and the age of cancer occurrence.

Cancer-specific distress. The intrusion subscale of the Impact of Event Scale¹¹ served as a measure of cancer-specific psychological distress. Items were modified to assess intrusive thoughts about breast cancer. For example "I had waves of strong feelings about it" became "I had waves of strong feelings about breast cancer". The authors report good internal consistency for the intrusive subscale, with coefficient alphas for two validation samples averaging .86.

Procedure

Women attending the Cancer Risk Evaluation Program (CREP), a clinic for the assessment and management of cancer risk, were recruited for this study. The majority of women come to the CREP clinic intending to get genetic testing, and testing is available to any woman who requests it, although not all women choose to proceed with testing after counseling

A total of 515 women received genetic counseling at the CREP clinic between January, 1995 and April, 1998. Of those 515, 137 were excluded from the survey due to a prior diagnosis

of cancer, and 28 declined participation in research. The remaining 350 women were mailed surveys, 28 of which were returned due to bad addresses, and 3 because the potential participant was deceased. A total of 248 surveys were returned, yielding a total response rate of 71%. For those choosing to have genetic testing, the survey was completed after counseling and receipt of test results. The average length of time between the initial clinic visit and completion of the follow-up survey was approximately 15 months. Neither risk perception nor psychological distress varied systematically by time from the clinic visit to follow-up survey.

RESULTS

Objective risk and subjective risk perception

Based on the Gail model of estimating prior probabilities for developing breast cancer, the average lifetime risk of breast cancer for this sample was 26.0% (SD = 17.4). Compared to the generally-accepted estimate of 11% lifetime risk of breast cancer in the general population, the women seeking help from the CREP high-risk clinic were indeed estimated to be at higher-risk.

As expected based on previous reports of numeric overestimates^{7,12}, women in this sample largely overestimated their lifetime numeric risk, averaging 49.1% (SD = 32.7). A paired t-test yielded a significant difference between objective risk estimates and numeric risk perception ($t = -8.07$, $p < .00$), illustrated in Figure 1.

Using the qualitative and comparative risk measures, however, women's estimates of their risk did not appear to be large overestimates. On a 5-point Likert scale, women estimated their risk to be an average of 3.45, or about midway between the anchor points "Neither high nor low" and "Moderately high". Similarly, women estimated their risk compared to the average woman to be about 3.91 (SD = .90), just below "Somewhat higher" than the average woman. Thus, participants seem to overestimate greatly their numeric risk, but not their qualitative or comparative risk estimates.

Risk perception and breast cancer worry

Women reported an average of 13.3 (SD = 6.14) on the intrusion subscale of the Impact of Event Scale¹¹. According to the scale norms suggested by the authors¹³, women in this sample reported intrusive thoughts that are related to moderate levels of psychological distress.

Correlations between intrusive thoughts about breast cancer and risk perception were similar across the three different measures. Examining the sample of women who provided all three risk estimates (n = 163), correlations between risk estimates and breast cancer-specific worry were similar, ranging from $r = .32$ to $r = .38$, all significant at $p < .001$,

IES scores were not significantly related to marital or employment status, or to ethnicity, but were significantly higher for women without a college education ($t = 3.75$, $p < .000$), and for women with a personal history of breast cancer ($t = -2.72$, $p = .007$). Accounting for breast

cancer status and education by entering these first into each of three hierarchical regression equations predicting IES from risk perception did not significantly change the results.

DISCUSSION

The data from the current study show that although women largely overestimated numeric probabilistic risk, they did not appear to largely overestimate qualitative and comparative risk. In isolation, and contrary to the prevailing philosophy in risk counseling, this result might suggest that qualitative risk estimates are a more accurate indicator of breast cancer risk perception. However, all three estimates of risk were equally related to breast cancer-specific worry. This suggests that although numeric risk estimates may be inflated relative to objective estimates, numeric scales are likely to provide different, rather than inferior or superior, risk perception information than qualitative estimates.

The finding that women seemed to overestimate numeric risk more than qualitative risk is consistent with results reported by other researchers, and supports the findings from the only other published comparison of numeric and qualitative estimates among the same women¹. However, several limitations of the current study require that these results be viewed as tentative pending replication. First, because of the metric of qualitative measures of risk perception, it is difficult to compare precisely the degree of risk overestimation made using qualitative measures to those made using a numeric measure. Second, the observed overestimation of numeric risk may be due to limitations in numeracy, or to lack of understanding of the risk of the average

woman, rather than to some fundamental difference in risk perception. Inclusion of a numeracy assessment, or an assessment of participants' estimates of the average woman's risk of breast cancer would have allowed more thorough analysis of these alternative hypotheses.

Limitations notwithstanding, these results have implications for genetic counseling. If counselors view risk based on objective, numeric estimates, and counselees tend to overestimate numeric risk, the discrepancy between counselor and counselee perceptions of risk may lead to misunderstandings. For example, Schwartz, Rimer, Daly, et al.¹⁴ report that less-educated participants receiving individualized breast cancer risk counseling were less likely to adhere to mammography screening recommendations than more educated participants, suggesting that perhaps the individualized interventions misspecified how women perceive their risk. This discrepancy in conceptualizing risk also may explain in part why inaccurate estimates persist even after cancer risk counseling in which accurate estimates are provided⁷.

Additionally, counselors may assume that overestimation of cancer risk signals risk for psychological distress, and that accurate numeric risk information is an antidote for apparent catastrophizing about breast cancer risk. However, despite the large overestimates of numeric risk reported by women in this sample, they did not report high levels of psychological distress, and distress was equally, although only moderately, related to all three measures of risk perception.

Taken together, the data from this study suggest that numeric probabilistic estimates of breast cancer risk should be seen as one of several indicators of breast cancer risk perception, rather than as a gold-standard measure. As such, relying solely on numeric risk estimates, either in conveying risk information, or in assessing risk perception, is likely to provide an incomplete view of a woman's sense of her breast cancer risk.

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Validity and Efficiency of Screening for History of Depression by Self-Report

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Abstract

The recurrent nature of depression has made personal history of the disorder a key consideration in clinical practice and research. There is a need for a means of screening for history of depression that is either valid in itself or an efficient means of identifying respondents in need of further assessment. The present study examined the validity and efficiency of assessment of lifetime history of depression by self-report in comparison with the results of a structured interview assessment conducted a year earlier. Self-report of a lifetime two weeks mood disturbance was unrelated to the results of the earlier interview. Self-report of treated episodes of mood disturbance were related to interview assessed history of depression, but this association was too small for practical applications. Self-report of past depression was more strongly related to concurrent distress than to the earlier interview assessment of history of depression. Implications of these findings for screening and assessment of history of depression are discussed.

It is increasingly apparent that major depression is a highly recurrent, episodic disorder (Frank & Thase, 1999; Judd, 1998). Consequently, a history of depression has emerged as an important variable for risk stratification in both clinical practice and research. Depression occurs relatively rarely in single episodes across a lifetime (Keller et al., 1983) and a prior episode of depression is an important predictor that someone will become depressed in the future (Coyne, Flynn, & Pepper, 1999). Underscoring that point, Eaton et al. (1997) found that when persons with prior histories of depression were eliminated from consideration, 23,698 person-years of study yielded only 71 new cases of major depression in 12- and 15- year follow-up assessments of participants in the Baltimore site of the Epidemiologic Catchment Area study.

In a 12-year prospective study of over 400 depressed patients seeking treatment in psychiatric treatment settings, Judd et al (1998) found that they spent 15% of this time meeting full criteria for major depression, and an even greater proportion of time with depressive symptomatology below threshold for major depression (Judd et al., 1998). The risk for depression associated with prior episodes is also so high that the Agency for Health Care Policy Research Depression Guidelines (Depression Guideline Panel, 1993) now recommends indefinite maintenance treatment with antidepressants for persons with three or more episodes.

It is now recognized that most depressed individuals do not receive treatment (Depression Guidelines Panel, 1993), and that even individuals who obtain treatment may have needlessly suffered for months before seeking help (Monroe, Simons, & Thase, 1991). Increasing the detection of untreated depression in the community and in primary medical care settings has been designated a major public health priority (Regier et al., 1988). There have also been calls for strategies to identify people who are presumed to be at risk for depression because of current distress, with the hope that preventive intervention could allow the suffering, personal impairment, and social costs associated with the disorder to be averted altogether (Munoz, Hollon, McGrath, Rehm, & Vandebos, 1994). The routine use of brief self-report measures has been seen as a key means of increasing detection of individuals who are either depressed and not receiving treatment, or who are at imminent risk of becoming depressed. However, proposed screening instruments such as the Center for Epidemiologic Studies-Depression Scale (CES-D; Radloff, 1977) and the Brief Symptom Inventory (BSI; Derogatis, 1993) are best construed as measures of general distress. They are too nonspecific and, therefore, too inefficient to provide cost-effective means of identifying depressed and at-risk individuals (Coyne, Thompson, Palmer, Kagee, & Maunsell, in press). After extensive review, the United States Preventive Task Force (1996) and the Canadian Task Force on

the Periodic Health Examination (1990) have recommended against the use of such instruments to screen for depression.

Given the recurrent nature of the disorder, however, tracking of individuals with histories of depression might prove more efficient than mass screening for current distress as a means of identifying at-risk and depressed individuals. Theory and research examining psychosocial factors in depression have only begun to take into account the overriding importance of prior episodes for subsequent development and current psychological functioning. The bulk of previous psychological theorizing has focused on psychosocial factors contributing to a person becoming depressed. Yet, depressed persons typically have already suffered numerous episodes of depression by the time they become available for study. Coyne et al. (1999) found that depressed research participants recruited from both primary medical care and outpatient psychiatric settings already averaged over 8 previous episodes of depression. The likelihood that few episodes of depression under study are first episodes requires attention to the direct, mediating, and moderating effects of past episodes of depression on current psychosocial circumstances and resources. For example, people with a history of depression are less likely to be currently married than are people without a history; if they are married, their first episode of depression is likely to have preceded their marriage; and they are substantially more likely to have a history of divorce. (For a review, see Coyne & Benazon, in press). Many

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psychosocial predictors of depression lose their significance once prior episodes of depression are taken into account. Kessler and Magee (1994) found this was the case for 13 of the 14 risk factors they examined.

Recognition of the importance of history of depression focuses attention on the need for valid and efficient means of screening for or assessing history of depression. A fundamental issue is whether a simple inquiry about prior depression is either valid in itself or an efficient means of identifying respondents in need of further assessment. Such quick and economical assessment strategies are increasingly desirable because of constraints on time and resources, but there are many reasons to believe that the task of assessing past depression may be more difficult than assumed. Efforts to identify current major depression by self-report have proven unsatisfactory; even when questions directly inquire about criterion symptoms (Zimmerman & Coryell, 1987), correspondence with semi-structured interview is poor (Coyne, 1994). Indeed, even diagnoses of current disorder based on questions administered by lay interviewers have only a modest correspondence to results of a semi-structured interview administered by a professional (Anthony et al., 1985).

Efforts to identify past episodes of depression are further complicated by problems of recall and the likelihood that respondents do not conceptualize relevant experience as a depressive episode with the same criteria as professionals would use. Problems in the

reporting of past psychopathology are demonstrated in findings that a third of persons who had been hospitalized for a psychotic disorder did not report this when assessed 11 years later (Pulver & Carpenter, 1983). However, a more recent study found that 25 years after an initial assessment, 70% of a sample of depressed individuals recalled having two weeks mood disturbance in the index period and 52% recalled enough symptoms to merit a retrospective diagnosis of major depression (Andrews, Anstey, Brodaty, Issakidis, Luscombe, 1999). There also has been evidence of inaccuracy in the ascertainment of history of depression in epidemiologic surveys (Aneshensel et al., 1987; Rice, Rochberg, Endicott, Lavori, & Miller, 1992). This may explain the paradox that lifetime reported rates of depression decline with age despite the expectation that they should increase because older persons have been at risk longer than younger persons (Robins, 1985). Perhaps, even more troubling is Dohrenwend's (1989) finding that 61% of the respondents who reported past major depression at baseline in the ECA study did not do so a year later. Aside from issues of recall, it may be that many persons do not construe an episode of depression as a discrete episode of disturbance. When depressed persons present to physicians, most do not identify themselves as depressed (Coyne et al., 1995).

The present study examined whether simple inquiries concerning history of depression corresponded to diagnoses of past depression which had been elicited in a semi-structured diagnostic interview a year earlier. A straightforward question on a self-

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report questionnaire concerning whether the respondent had ever experienced two weeks period of mood disturbance was evaluated alone and in combination with questions whether, if a mood disturbance had ever occurred, it impaired interpersonal relations or had been treated with therapy or medication. The null hypothesis of no relation between the inquiry concerning mood disturbance and results of the diagnostic interview strains credibility. Yet, the important question is not whether a statistically significant association can be found, but whether the simple inquiry is valid and clinically efficient. With sufficient sample size, it is possible to obtain a highly significant statistical association even when the absolute level of agreement with a criterion variable is so low as to make use of a screening approach inefficient and impractical. The relation between a simple inquiry and results of a clinical interview can be expressed in terms of the sensitivity and specificity of the inquiry concerning mood disturbance (Fletcher, Fletcher, & Wagner, 1988; Zarin & Earls, 1993). Sensitivity refers to the proportion of persons with a history of depression answering affirmatively to the self-report inquiry concerning mood disturbance. Specificity refers to the proportion of persons without a history of depression who respond in the negative to the self-report inquiry. For the purposes of evaluating the use of the mood disturbance questions for the purposes of screening, an additional summary statistic is informative, the positive predictive value. This refers to the proportion of persons who respond affirmatively to the self-report inquiry who have a

history of depression. It depends upon the prevalence of the disorder, as well as the specificity and sensitivity of the inquiry (Fletcher et al., 1988).

It may be unrealistic to assume an excellent correspondence between a simple inquiry concerning history of depression and the results of a more systematic interview. Yet, such an inquiry might still be efficient as a first step in a two-stage assessment procedure if the inquiry had good sensitivity, even if poorer specificity (Newman, Shrout, & Bland, 1990). With appropriate weighting of the resulting data, such a two-stage procedure would actually produce more accurate estimates of the prevalence of history of depression than performing the same number of interviews with an unscreened sample of the same size (Shrout, Skodal, & Dohrenwend, 1986). For clinical purposes, an inquiry concerning history of depression could be useful even with less than optimal sensitivity, if it had good specificity. A clinician getting an affirmative answer from a patient concerning a history of depression could presumably be confident that the patient had been previously depressed, even if a concern remained that significant numbers of patients with such a history were being missed with such a strategy. However, our evaluation of the sensitivity and specificity of inquiries concerning history of depression ought to be qualified by any evidence of systematic biases in the responses to such inquiries. For instance, it would be problematic if patients' recall of past depression were found to be unduly influenced by their current psychological state, a possibility we

examined in this study. Such a finding would raise troubling questions about the validity of the inquiry concerning past depression, even in the context of a positive agreement with a criterion interview-based assessment of prior depression.

Methods

Sample and Recruitment Procedure

The sample consisted of 323 women drawn from the registry of the Hereditary Breast and Ovarian Cancer Study conducted by the University of Michigan and the University of Pennsylvania Cancer Center (See Coyne et al., in press, and Coyne and Anderson, in press for further details). The initial measure of self-reported distress and diagnostic interview data reported in this paper are derived from baseline assessments obtained from these women starting in the year after the announcement that a strong candidate for the breast and ovarian cancer susceptibility gene, BRCA1, had been identified (Miki et al., 1994). At the time of the baseline assessment, the offering of genetic testing to these women for risk of breast and ovarian cancer was widely expected to be imminent. There were concerns about the psychological vulnerability of the women, and whether distress and depression associated with their high-risk status would interfere with their abilities to become informed about the risks and benefits associated with receiving test results, to provide a fully informed consent to receiving these results, and to cope with the possibility that they would be found to have an altered gene associated with

greater risk of cancer. There was also a need to obtain baseline data so that any psychological effects of subsequent testing could be identified.

Women enrolled in the registry were asked to complete a baseline questionnaire including a measure of distress, a 25-item version of the Hopkins Symptom Checklist (HSCL-25; Hesbacher, Rickels, Downing, & Stepansky, 1978). They then received a telephone interview including the mood disorders, anxiety, and alcohol use modules of the Structured Clinical Interview for DSM-IV (SCID-IP; First, Spitzer, Williams, & Gibbon, 1995). Over the course of the next year, it became apparent that as a result of technical and logistical problems, it would still not yet be possible to offer many of these women information whether they carried a mutation of BRCA1 conferring increased risk for cancer. An interim one-year assessment of women not yet receiving results of genetic screening was, therefore, introduced to monitor psychosocial and mental health variables which might be subject to change in the intervening period. This assessment by a mail-back self-report questionnaire packet included the HSCL-25 and the queries concerning past depression used in the present article.

Measures.

Depression Screening Questions. The inquiry concerning past depression started with a question taken directly from the Diagnostic Interview Schedule (DIS; Robins, Helzer, Croughan, & Ratliff, 1981) and assessed two-week mood disturbance and

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associated impairment. The first question was:

Have you ever in your life had two weeks or more when, nearly every day, you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun?

If there had been such a period, three separate follow-up questions inquired (a) whether the respondent's work or relationships suffered, (b) whether the respondent had received counseling or psychotherapy, or (c) whether the respondent had received medication for this condition.

Rost, Burnam, and Smith (1993) had previously reported sensitivity in excess of .80 and specificity in excess of .90 for a pair of screening questions assessing current depressed mood and anhedonia with respect to a simultaneously obtained diagnosis of major depression using the DIS (Robins et al., 1981). Although these figures suggest some promise for these questions as a means of screening for depression, they may have been inflated by their direct correspondence to the questions in the DIS. Unlike the SCID (First et al., 1995), the DIS is basically a lay interviewer-administered questionnaire, and does not allow for interviewer probes of responses (Coyne, 1994).

Psychological distress. The 25-item version of the Hopkins Symptom Checklist (HSCL-25) was used to assess psychological distress. The scale includes uses 10 items from the HSCL-90 anxiety cluster, 13 items from the depression cluster, and two

additional somatic symptoms (poor appetite; and difficulty falling asleep or staying asleep). The same items also appear with inconsequential differences in wording on the Symptom Checklist 90 (SCL-90; Derogatis & Cleary, 1977). Hesbacher et al. (1978) found that the HSCL-25 correlated highly with the standard 58-item version Hopkins Symptom Checklist (Derogatis et al., 1974). The HSCL-25 has been widely used for the psychiatric screening of medical patients (Fink et al., 1995). With a cutoff of 44 for caseness, Hough et al. (1982) found that the HSCL-25 was comparable or superior to the CES-D (Radloff, 1977) in detecting psychiatric disorder, depending on the criterion employed. Consistent with past studies, coefficient alpha for the HSCL-25 was found to be .91.

Interview-based measures of psychiatric morbidity. Semi-structured interviews were conducted to assess current and past history of depression, anxiety, and alcohol use. Because of its modular construction, the SCID can be adapted for use in studies in which only a particular diagnosis is of interest (First et al., 1995). The mood disorders, anxiety, and alcohol use modules of the SCID were utilized in this study. The administration of the SCID was done by telephone because many of the participants were from out of state. Previous studies have shown the concordance of telephone-administered diagnostic interviews with face-to-face interviews for assessment of depression (Baer, Brown-Beasley, Sorce, & Heenriques, 1993; Kendall, Neale, Kessler, Heath, & Eaves, 1992; Potts,

Daniels, Burnham, & Wells, 1990; Wells, Burnam, Leake, & Robins, 1988). Also, Slutske et al. (1998) recently showed that the reliability and validity of alcoholism diagnoses and symptoms by telephone assessment is as good as what is obtained in face-to-face interviews. Concurrent with the present project, we conducted a reliability study comparing interviewers' diagnoses and ratings of diagnosis and symptoms of depression to independent raters using 28 audiotapes of telephone assessments. The interviewers included some of those employed in the present study, but the sample of interviewers and tapes was not limited to this study. There was 100% agreement for diagnosis, and 97% agreement for specific symptoms. Although an inter-rater agreement study was not conducted for the present project, another concurrent study in the same laboratory found an 80% agreement for history of depression (Coyne et al., 1999).

Results

Basic Demographics.

The women in the sample were in their late forties ($X = 49.9$, $S.D. = 12.2$) and they were predominantly White (98.1%), Christian (80.3%), married (74.9%), and had an average of two children. One striking characteristic of this group is their high level of education and income. Most women had at least some college, worked outside the home, and had an annual family income that exceeded \$54,000. These results are consistent with previous findings that women who seek genetic testing are generally well educated

and have a higher social economic status (Codori, Hanson, & Brandt, 1994; Kash, Holland, Osborne & Miller, 1995).

Women who reported a history of depression in the SCID interview were younger than those who did not report a history of depression (mean age= 46.5 years vs. mean age= 49 years, $t= 2.07$, $p < .05$). They did not differ from those who did not report a history of depression on any other demographic variables (ethnic background, marital status, number of children, or education level).

Women who reported a history of depression in the simple self-report did not differ from those who did not on a number of demographic variables. There were no differences in age, ethnic background, marital status, number of children, and education level between those women who reported a history of depression on self-report and those who did not.

Prevalence of Past History According to Semi-Structured Interview and Simple Self-Report.

According to the semi-structured interview, 66 (20%) of the women had a history of depression. The simple self-report concerning past two weeks mood disturbance yielded a much higher number of women reporting a history of depression (148, or 45%). Not only were the estimates of prevalence vastly different between semi-structured interview and simple self-report, but there was not significant overlap between semi-structured

interview and simple self-report in terms of who had a history of depression and who did not, $\chi^2 (1, n=323) = .51, n.s.$ The correspondence between self-report and structured interview of history of depression is shown in Table 1. It is noteworthy that only 48% of the women who had been found to have a history of depression in the interview reported a lifetime two weeks mood disturbance in the later self-report assessment. Specificity for the simple self-report was a modest 56.4 % and sensitivity was even worse (48.5 %). Positive predictive value was only 22.2 %. However, interpretation of all these measures of performance needs to be qualified by noting that the relation between the screening question and interview-assessed history of depression did not depart from chance.

Insert Table 1 about here

Effects of Including Impairment Criteria in Defining Past Depression.

As noted above, the query about past history of depression was followed by three "If yes,..." probes providing multiple means of meeting an impairment criterion. The prevalence of reported past depression based on affirmative response to the mood disturbance question and to any of the impairment questions was 38%. Affirmative response to any of the impairment probes increased sensitivity of report of past

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depression to 63%, but reduced specificity to 43% with respect to the earlier interview.

Positive predictive value remained modest (23%). The relationship between the qualified self-report and SCID-detected history of depression remained non-significant, $\chi^2 (1, n=316) = .90$, n.s. An affirmative answer to the mood disturbance question and the probe "If yes, did your work or relationships suffer?" provided a prevalence of past depression of 33%. It increased specificity to 68%, and reduced sensitivity to 36%. Positive predictive value remained unchanged (23%). The relationship between self-report of past depression qualified in this way and SCID-detected history of depression remained non-significant, $\chi^2 (1, n=321) = .50$, n.s.

Including only the more stringent "If yes, did you get counseling or psychological treatment?" qualifier provided a prevalence of past depression of 24%. It increased specificity to 78%, and reduced sensitivity to 34%. Positive predictive value was increased modestly (29%). The relationship between self-report qualified in this way and SCID-detected history of depression was significant, $\chi^2 (1, n=318) = 4.13$, $p < .05$.

Including only the "If yes, did you get medication for this problem?" qualifier increased specificity to 86%, and reduced sensitivity to 27%. Positive predictive value was increased modestly (32%). The relationship between self-report qualified in this way and SCID-detected history of depression was significant, $\chi^2 (1, n=318) = 5.73$, $p < .05$.

However, the strength of this finding was driven by most women not having a history of

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depression and most of these women (85.7%) indicating that they had not had a two week mood disturbance for which they received medication. Thus a statistically significant association was not the basis of a clinically useful screening tool.

Two of the qualifiers ("If yes, did you get counseling or psychological treatment?" and "If yes, did you get medication for this problem?") were combined to make up a help-seeking qualifier. Women who endorsed either counseling or medication use were considered to have reported help-seeking. The help-seeking qualifier provided a past prevalence of 28%. It had a specificity of 74%, a sensitivity of 38%, and a positive predictive value of 27%. The relationship between self-report qualified in this way and SCID-detected depression was marginally significant, $\chi^2 (1, n = 313) = 3.62, p < .06$.

Effects of Current Psychological State on Report of Past Depression.

As seen in Table 2, women who reported a past episode of depression in the SCID interview were more likely to have been distressed according to a standard cut-score of 44 on the HSCL-25 than were women who did not report prior depression, $\chi^2 (1, n = 323) = 21.31, p < .001$. This relation held even when the few (2%) women were excluded who met criteria for current major depressive disorder, $\chi^2 (1, n = 317) = 16.13, p < .001$.

Insert Table 2 about here

Women who reported a past episode of depression in the self-report inquiry were more likely to have been distressed according to a concurrently administered HSCL-25 than women who did not report prior depression, $\chi^2 (1, n = 323) = 34.21, p < .001$.

Finally, to examine the possibility that highly distressed women are sensitized to remember past episodes of depression, we examined the relationship between SCID-detected and self-report history of depression in women who had elevations above the cut-score on the HSCL-25. There was no significant relationship between SCID-detected and self-report history of depression in this group of women, $\chi^2 (1, n = 63) = 1.96, n.s.$

Discussion

This study sought to evaluate whether it is justifiable to use a simple retrospective self-report inquiry as an indicator of history of depression for clinical and research purposes. The self-report questions were compared to results of a semi-structured diagnostic interview conducted a year earlier and to a concurrently administered self-report measure of distress. We had set a number of criteria for evaluating the validity and efficiency of such self-reported history of depression. Specifically, with a sample of over 300 women, the issue was not whether a statistically significant relation between self-report and the earlier interview would be found, but whether the sensitivity, specificity, and positive predictive value of the self-report questions would be such that they could be applied validly and efficiently in clinical and research settings. Even if performance of

the self-report did not justify its use to classify patients or research participants, it might still have been sufficient to serve as the first stage in a two-stage process of screening and follow-up interview. However, we not only found the performance of the self-report questions unsuitable for such applications, we also unexpectedly failed to find more than a chance relation between the self-report questions and the earlier diagnostic interview. The exception to a pattern of null findings was a modest, but statistically significant, relationship between self-report of a lifetime mood disturbance for which treatment was sought and an earlier interview finding of a history of depression. Despite statistical significance, using this self-report of treated mood disturbance would result in considerable misclassification of patients or research participants. Among our disconcerting findings was that most women who were found to have a history of depression in the interview no longer reported two weeks period of mood disturbance in their lifetime in an assessment by questionnaire a year later. This replicates findings reported by Dohrenwend (1989). Also troubling, we found significant relations between reports of a history of mood disturbance and concurrent distress. As an indicator of history of depression, at least by the criterion we had chosen, the self-report questions were not very useful and potentially misleading.

Before discussing potential implications of these findings, it is important to consider how some features of this study might be relevant to the strength and generality

of the conclusions we might draw. First, there is the criticism that there is no "gold standard" for past history in this study; we only have a comparison between self-report and an earlier interview. Although the issues are complex, some credibility should be granted to this criticism. We can not ascertain the validity of the interview assessment of past history, particularly at the level of using it to classify individuals. However, in many contexts, interview assessment is all that is possible, and it remains an important question as to whether self-report can serve as an equivalent or a first stage screening to make decisions about whom to interview.

A second issue that could be raised is that there was a year between the interview assessment of history of depression and the self-report of history of mood disturbance that we attempted to validate against it. Might the development of distress and depression in this year explain the discrepancy between results of the interview and the later self-report of history of depression? A number of factors suggest that this was unlikely to be a major factor in the results that were obtained. First, the prevalence of current major depression at the first assessment was so low as to suggest a quantum increase in incident depression would have been needed to create a substantial discrepancy between these earlier and later ascertainties of depression. Yet, in this same time period, there was no increase in mean psychological distress for the sample. Also, in this age range, first episodes of depression are relatively uncommon, so one-year incidence could not be a

strong influence on the self-report of history of depression. Therefore, depression in the year between the interview and the self-report assessment may attenuate the relations we found, but it is unlikely to be the major determinant of the weakness of our results.

A third challenge to the validity and generalizability of the results is that the self-report of history of depression concerned only two weeks mood disturbance and not the additional symptoms needed for a diagnosis for depression. This could readily affect the specificity of the screening questions, but should not affect their sensitivity, which was unacceptably low. Furthermore, the introduction of impairment criteria in the self-report should have compensated at least in part for the lack of assessment of additional symptoms of depression. Presumably, occurrence of a full syndrome of depression would be more strongly associated with impairment of interpersonal relationships and the receipt of treatment than would two weeks mood disturbance without additional symptoms.

A fourth criticism of our study is the representativeness of our sample. We studied a rather select sample of women, presumably at high risk of breast and ovarian cancer based on family history, while they were awaiting genetic testing potentially informative of their actual risk for cancer. Yet, a previous study of the larger registry from which the present sample was drawn revealed the women to be no more distressed than primary medical care samples and well within range of epidemiological findings for lifetime and

current prevalence of depression (Coyne et al., in press). With respect to current distress and depression at the point of initial assessment, they were not an unusual group of women.

A final challenge to broad interpretations of the results which were obtained is that the questions concerning history of depression were embedded in a larger survey instrument and they may not have been given the careful reflection which they would have in other contexts, notably a clinical interview. We believe that, for some purposes, this is a valid criticism. There are reasons to believe that the results obtained with a self-report instrument could indeed be different from what is obtained in the context of a formal interview or in the process of help-seeking. For example, Helzer et al. (1985) suggest that making an appointment for treatment and talking with a clinician may trigger memories of past depression. The clinician-patient interaction may also serve to allay the patient's concerns about disclosing past depression, including fears of being stigmatized, thereby increasing disclosure. There are two empirically testable hypotheses being raised here. The first is that the clinical context enhances recall of history of depression, regardless of how this history is assessed. The second is that clinician-patient interaction may facilitate the disclosure of history of depression. These hypotheses deserve further investigation.

However, it is important for other purposes to note that individuals seeking treatment are a biased sample of all depressed persons, and the particular episodes of depression they recall also may be a biased sample. Selective filters determining who seeks treatment for depression in specialty settings (Goldberg & Huxley, 1992) include severity of current depression and severity of course, including prior treatment and the number and severity of past episodes of depression. Individuals who seek treatment are likely to have more severe episodes of depression to report, and they may selectively recall the most severe episodes. Issues of potential selection bias are confounded with issues concerning the differences in the characteristics of depression found in specialty mental health versus other settings. Episodes of depression reported by patients in mental health settings typically last months or years, whereas episodes reported by individuals recruited from other settings tend to have lasted weeks or a few months.

Our results do not support use of questions concerning mood disturbance and impairment embedded in a larger survey either as a means to identify respondents as having a history of depression or as the first stage in selecting them for further interview assessment. It remains to be seen to what range of contexts and assessment strategies our disheartening results generalize. Even though administered by lay interviewers, instruments such as the DIS (Robins et al, 1981) may be susceptible to at least some of the problems encountered in the present study. Such instruments are essentially

interview-administered questionnaires, with no opportunity for interviewers to explain questions or response options or probe responses. Furthermore, diagnosis of current depression using the DIS depends upon first establishing lifetime depression, and this, in turn, depends on answers to the same questions concerning lifetime two weeks mood disturbance used in the current study. Using DIS data from the Epidemiologic Catchment Area study, Kessler and McGee's (1994) reported " odds ratio close to 40.0" (p. 243) for prior depression predicting current depression in a community sample. Prospective studies also reveal that depression is highly recurrent (Judd et al., 1998). We are inclined to explain some of the extraordinary strength of Kessler and McGee's (1994) findings as the result of a confounding of current mood disturbance with recall of past depression. Taken together with our present findings, these results stand as a caution against uncritically accepting results of research where such biases may be operating.

History of depression is a crucial consideration in clinical practice and research, despite the difficulties we have shown in its assessment. One implication of our findings is that, wherever possible, use of records of past depression is to be strongly preferred over a reliance on respondent recall. For instance, the treatment depression among primary care patients should be recorded in a way that allows ready identification of such patients in the future. Yet, given our results, what can we recommend for assessment of past depression in the many contexts where independent validation of respondent reports

is not available? We also believe that the validity should be examined of a simple inquiry concerning past depression made in the context of a supportive interview. Chochinov, Wilson, Enns, and Lander, (1997) demonstrated the satisfactory performance of a simple inquiry of terminally ill medical patients concerning depressed mood and anhedonia with respect to results of a formal semi-structured interview, as well as the superiority of this inquiry over self-report screening instruments. It is not clear whether the critical factor was the rapport that was established or the opportunity to discuss the questions and patients' responses. Regardless, such interview assessment of current depression may be more efficient than screening with self-report questionnaires (Coyne et al., in press), and our results suggest that an even stronger case might be made for the interview assessment of lifetime depression, given the poor performance of self-report.

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Table 1

Correspondence Between Self-Report and Structured Interview of History of

Depression.

	SCID	SCID
Self-Reported	No History	History
No History	112	32
History	145	34

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Table 2

Correspondence Between Hopkins Distress and Structured Interview of History of

Depression

	SCID	SCID
Hopkins	No History	History
Not Distressed	217	43
Distressed	50	23

RUNNING TITLE: Numeric, qualitative, and comparative risk perception

Comparison of numeric, qualitative, and comparative measures of breast cancer risk perception.

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ABSTRACT

Perception of breast cancer risk is thought to be an important determinant of health-care decision-making, screening behavior, and psychological distress among women with family histories of breast cancer. Cancer risk counseling aims to assist women in accurately estimating their risk. Published guidelines currently suggest that cancer risk counseling convey numeric estimates of risk rather than ambiguous qualitative estimates, although women seem to be more accurate in estimating their qualitative risk than their numeric risk. The current study investigated the relative accuracy of numeric, qualitative, and comparative risk estimates, and the relationship of these estimates to cancer-specific distress. Women attending a high-risk cancer clinic (n=248) completed mailed surveys after receiving cancer risk counseling. Surveys assessed breast cancer risk perception as a percentage (numeric), as a Likert-type scale from low to high (qualitative), and compared to the average woman (comparative), as well as distress assessed by the IES, and other health services issues. Women significantly overestimated their numeric risk relative to objective risk estimates, but did not appear to overestimate greatly their qualitative or comparative risk. Additionally, on average women reported moderate levels of cancer-specific distress, and all three measures of risk perception were equally related to distress. Taken together, these results suggest that cancer risk counselors may be mistaken in relying solely on numeric risk estimates for conveying risk or assessing risk perception, and that overestimation of numeric risk does not necessarily indicate debilitating psychological distress.

INTRODUCTION

Risk perception figures heavily in the cancer risk counseling of women with family histories of cancer, and in the assessment of counseling effectiveness. Accuracy in a woman's perception of breast cancer risk is considered an important aspect of informed decision-making, a determining factor for screening behavior, and an antidote for excessive psychological distress¹. Additionally, the accuracy of participants' estimates of their risk of developing cancer obtained after counseling is often used as an indicator of counseling effectiveness.

The two most common methods of estimating objective breast cancer risk are models developed by Gail² and Claus³ both of which express risk in terms of a numeric probability or percentage. Published guidelines for genetic counselors emphasize the importance of communicating numeric risk⁴, and caution against the use of qualitative estimates of risk that might impose the counselor's values or otherwise violate a participant's self-determination^{5,6}.

The assumption underlying the use of numerical probability estimates is that counseling participants understand probability estimates, and that these provide a value-neutral scaling system for communicating risk. However, there is ample evidence that many people have difficulty interpreting quantitative data such as probabilities, which requires a cognitive ability termed "numeracy". For example, one study of women with a family history of breast cancer found that over 90% of women overestimated their numeric risk of developing breast cancer relative to objective Gail estimates, and that 66% of these women "extremely overestimated"

their risk⁷. A study by Schwartz⁸ found that a sample of female veterans performed poorly on numeracy tasks, and that the majority of women were unable to interpret numerical data about the reduction in risk of breast cancer death associated with use of mammography. Women with higher numeracy scores more accurately estimated the average risk of dying from breast cancer, and were better able to interpret numerical data about risk reduction. Another community study⁹ and a review by Woloshin et al.¹ report similar findings regarding poor numeracy, and the association between numeracy and accuracy of risk perception.

An alternative to numeric estimates of risk are qualitative measures, such as one's risk relative to the average woman, or one's risk on a continuum from low to high. Although the prevailing philosophy in cancer risk and genetic counseling has been to avoid such qualitative estimates of risk, such conceptions of risk may be important in participants' comprehension of risk. For instance, the finding that participants in cancer risk counseling have difficulty interpreting numeric probabilities, even after counseling that provides accurate risk estimates^{7,10}, suggests that risk is not simply a numeric construct for participants. Additionally, in comparing studies employing numeric or qualitative measures of risk perception, Woloshin, et al.¹ concluded that respondents were more accurate in estimating qualitative risk than they were in estimating quantitative risk.

The present study examined the concordance of numeric risk estimates to qualitative and comparative estimates among women who had received counseling concerning their personal

risk of breast cancer. A high concordance among these measures would suggest that different ways of assessing risk tap into a common risk perception construct. This study also compared numeric risk estimates to objective calculations of risk provided in counseling, and compared the relative accuracy of numeric, qualitative, and comparative risk estimates. Based on the results of previous research, we expected that numeric risk estimates would be overestimates relative to objective risk estimates. Finally, this study examined the degree to which different measures of risk perception were related to breast cancer-specific distress, one indicator of the utility of a particular measure of risk perception.

METHOD

Participants

A total of 248 women attending the Cancer Risk Evaluation Clinic for assistance in evaluating and managing their cancer risk participated in the present study. The average age of participants was 53 years ($SD = 10.58$), ranging from 21 to 88 years. Most participants were married (81.2%), Caucasian (71.7%), and college-educated (72.1%). About one-third had a personal history of breast cancer (27.9%).

Measures

Risk perception. Women were asked to estimate their chances of developing breast cancer at some point in their lifetime using three different measures: 1) a visual analog scale ranging from 0 to 100% chance of developing breast cancer (numeric); 2) a 5-point Likert-type

scale ranging from very low to very high chance (qualitative); and 3) a 5-point Likert-type scale ranging from much lower to much higher chance compared to the average woman (comparative). These represent the most common types of risk assessments used in previous studies¹.

Objective risk. Estimates of objective risk were calculated from participants' pedigrees collected as part of standard clinic practice, and based on the Gail, et al model². Gail risk estimates take into account the number of first- and second-degree relatives affected with breast cancer, and the age of cancer occurrence.

Cancer-specific distress. The intrusion subscale of the Impact of Event Scale¹¹ served as a measure of cancer-specific psychological distress. Items were modified to assess intrusive thoughts about breast cancer. For example "I had waves of strong feelings about it" became "I had waves of strong feelings about breast cancer". The authors report good internal consistency for the intrusive subscale, with coefficient alphas for two validation samples averaging .86.

Procedure

Women attending the Cancer Risk Evaluation Program (CREP), a clinic for the assessment and management of cancer risk, were recruited for this study. The majority of women come to the CREP clinic intending to get genetic testing, and testing is available to any woman who requests it, although not all women choose to proceed with testing after counseling

A total of 515 women received genetic counseling at the CREP clinic between January, 1995 and April, 1998. Of those 515, 137 were excluded from the survey due to a prior diagnosis

of cancer, and 28 declined participation in research. The remaining 350 women were mailed surveys, 28 of which were returned due to bad addresses, and 3 because the potential participant was deceased. A total of 248 surveys were returned, yielding a total response rate of 71%. For those choosing to have genetic testing, the survey was completed after counseling and receipt of test results. The average length of time between the initial clinic visit and completion of the follow-up survey was approximately 15 months. Neither risk perception nor psychological distress varied systematically by time from the clinic visit to follow-up survey.

RESULTS

Objective risk and subjective risk perception

Based on the Gail model of estimating prior probabilities for developing breast cancer, the average lifetime risk of breast cancer for this sample was 26.0% (SD = 17.4). Compared to the generally-accepted estimate of 11% lifetime risk of breast cancer in the general population, the women seeking help from the CREP high-risk clinic were indeed estimated to be at higher-risk.

As expected based on previous reports of numeric overestimates^{7,12}, women in this sample largely overestimated their lifetime numeric risk, averaging 49.1% (SD = 32.7). A paired t-test yielded a significant difference between objective risk estimates and numeric risk perception ($t = -8.07$, $p < .00$), illustrated in Figure 1.

Using the qualitative and comparative risk measures, however, women's estimates of their risk did not appear to be large overestimates. On a 5-point Likert scale, women estimated their risk to be an average of 3.45, or about midway between the anchor points "Neither high nor low" and "Moderately high". Similarly, women estimated their risk compared to the average woman to be about 3.91 (SD = .90), just below "Somewhat higher" than the average woman. Thus, participants seem to overestimate greatly their numeric risk, but not their qualitative or comparative risk estimates.

Risk perception and breast cancer worry

Women reported an average of 13.3 (SD = 6.14) on the intrusion subscale of the Impact of Event Scale¹¹. According to the scale norms suggested by the authors¹³, women in this sample reported intrusive thoughts that are related to moderate levels of psychological distress.

Correlations between intrusive thoughts about breast cancer and risk perception were similar across the three different measures. Examining the sample of women who provided all three risk estimates (n = 163), correlations between risk estimates and breast cancer-specific worry were similar, ranging from $r = .32$ to $r = .38$, all significant at $p < .001$,

IES scores were not significantly related to marital or employment status, or to ethnicity, but were significantly higher for women without a college education ($t = 3.75$, $p < .000$), and for women with a personal history of breast cancer ($t = -2.72$, $p = .007$). Accounting for breast

cancer status and education by entering these first into each of three hierarchical regression equations predicting IES from risk perception did not significantly change the results.

DISCUSSION

The data from the current study show that although women largely overestimated numeric probabilistic risk, they did not appear to largely overestimate qualitative and comparative risk. In isolation, and contrary to the prevailing philosophy in risk counseling, this result might suggest that qualitative risk estimates are a more accurate indicator of breast cancer risk perception. However, all three estimates of risk were equally related to breast cancer-specific worry. This suggests that although numeric risk estimates may be inflated relative to objective estimates, numeric scales are likely to provide different, rather than inferior or superior, risk perception information than qualitative estimates.

The finding that women seemed to overestimate numeric risk more than qualitative risk is consistent with results reported by other researchers, and supports the findings from the only other published comparison of numeric and qualitative estimates among the same women¹. However, several limitations of the current study require that these results be viewed as tentative pending replication. First, because of the metric of qualitative measures of risk perception, it is difficult to compare precisely the degree of risk overestimation made using qualitative measures to those made using a numeric measure. Second, the observed overestimation of numeric risk may be due to limitations in numeracy, or to lack of understanding of the risk of the average

woman, rather than to some fundamental difference in risk perception. Inclusion of a numeracy assessment, or an assessment of participants' estimates of the average woman's risk of breast cancer would have allowed more thorough analysis of these alternative hypotheses.

Limitations notwithstanding, these results have implications for genetic counseling. If counselors view risk based on objective, numeric estimates, and counselees tend to overestimate numeric risk, the discrepancy between counselor and counselee perceptions of risk may lead to misunderstandings. For example, Schwartz, Rimer, Daly, et al.¹⁴ report that less-educated participants receiving individualized breast cancer risk counseling were less likely to adhere to mammography screening recommendations than more educated participants, suggesting that perhaps the individualized interventions misspecified how women perceive their risk. This discrepancy in conceptualizing risk also may explain in part why inaccurate estimates persist even after cancer risk counseling in which accurate estimates are provided⁷.

Additionally, counselors may assume that overestimation of cancer risk signals risk for psychological distress, and that accurate numeric risk information is an antidote for apparent catastrophizing about breast cancer risk. However, despite the large overestimates of numeric risk reported by women in this sample, they did not report high levels of psychological distress, and distress was equally, although only moderately, related to all three measures of risk perception.

Taken together, the data from this study suggest that numeric probabilistic estimates of breast cancer risk should be seen as one of several indicators of breast cancer risk perception, rather than as a gold-standard measure. As such, relying solely on numeric risk estimates, either in conveying risk information, or in assessing risk perception, is likely to provide an incomplete view of a woman's sense of her breast cancer risk.

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Author Note

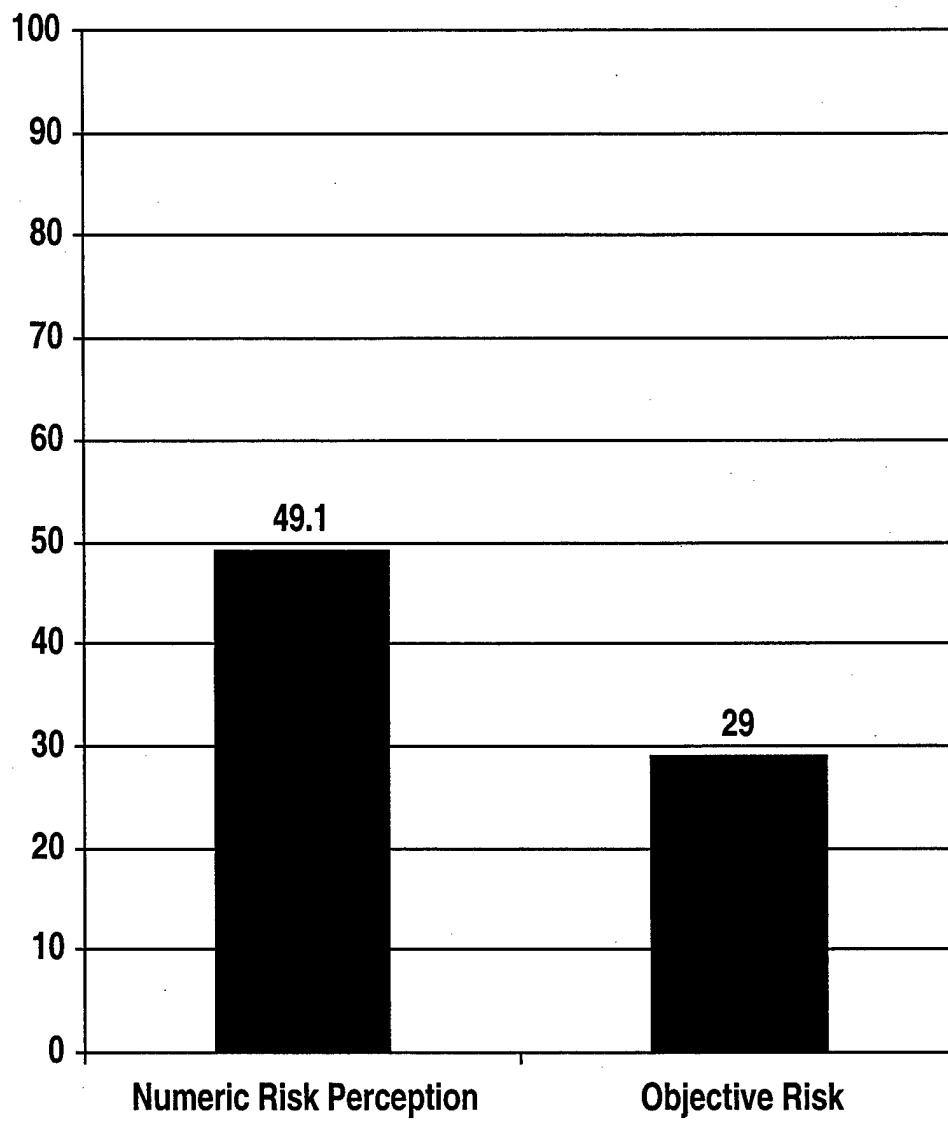
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Figure 1.
Overestimation of risk.



**THE EUNICE AND IRVING LEOPOLD ANNUAL
SCIENTIFIC SYMPOSIUM AND RETREAT**

**UNDERSTANDING RISK PERCEPTION AMONG WOMEN ATTENDING THE
CANCER RISK EVALUATION PROGRAM**

M. W. Racioppo, K. Armstrong, L. K. Kruus, & J. C. Coyne

Women with a family history of breast cancer who seek risk counseling are widely portrayed as overestimating their risk of breast cancer and as being a psychologically vulnerable population. However, the limited research literature on which this stereotype is based is characterized by a number of methodological problems. Namely, there are inconsistencies in the measures of perceived risk that have been employed and they typically do not have established empirical validity. Furthermore, inferences about the level of psychological distress among these women have been made in the absence of appropriate normative comparisons. The present study addressed these problems by including multiple measures of risk perception and by introducing a direct comparison between levels of distress in the study sample and what has been found in other diverse populations. The sample consisted of 348 women attending a high-risk cancer clinic. All women completed three conventional self-report measures of perception of lifetime breast cancer risk: 1) a visual analog scale anchored with numerical percentages; 2) a 5-point Likert-scale anchored with adjectives from very low to very high; and 3) a 5-point Likert- scale involving self-comparison to the average woman. They additionally completed the intrusion subscale from the Impact of Event Scale; Horowitz, Wilner, & Alvarez, 1979) as a measure of distress. Finally, an estimate of objective risk of breast cancer was calculated using the Gail model. The women were found to overestimate their risk of breast cancer relative to the objective estimate. Yet, they perceived themselves as at lower risk than the average woman, and there was only a modest intercorrelation among the alternative measures of risk. Perceived risk was only modestly related to distress, and mean levels of distress were lower than relevant comparison samples. These results call into question the convergent validity of existing measures of risk perception and add to concerns about the substantive interpretation of self-report risk perception data. Although counter to existing stereotypes, findings concerning psychological distress among these women are consistent with other emerging findings that high-risk women are not psychologically distressed as a group.

DISTRESS IN ANTICIPATION OF *BRCA1/2* TESTING: SOME RELEVANT COMPARISONS

L. K. Kruus, M. W. Racioppo, Ph.D., & J. C. Coyne, Ph.D.

Existing data suggest that women receiving testing for the *BRCA1/2* mutations are self-selected for psychological adjustment and that the revelation of positive risk status does not have lasting negative psychological consequences. Nonetheless, there is a stereotype that women with familial risk of breast cancer are psychologically vulnerable and that genetic testing carries substantial risk of psychological morbidity. This is in part based on selective attention to studies which do not employ standardized measures of distress or which neglect to make relevant population comparisons. The present study examined self-ratings of distress associated with various threats, including: (a) being a member of a high-risk family; (b) being offered testing; and the possibility of testing (c) negative or (d) positive for a gene mutation. Additionally, level of distress associated with the possibility of developing breast cancer was examined among women without a breast cancer history, and distress related to receiving a breast cancer diagnosis was examined among those with a history of the disease. Moreover, the association of this threat-related distress with well-validated measures of personal and social functioning, general psychological distress, and interference with daily life was explored.

Participants were 470 women selected from the Hereditary Breast and Ovarian Cancer Study by the University of Pennsylvania Cancer Center and the University of Michigan. The sample ranged in age from 19 to 86 ($M = 48.5$) and was predominantly Caucasian, well educated, married, and of high SES. Forty-five percent of women had a history of breast cancer (M years since diagnosis = 8.24).

Analyses revealed a distress by breast cancer status interaction ($p < .05$). Specifically, for women with a history of breast cancer, the level of distress associated with receiving a diagnosis of breast cancer was greater than all other threats, and distress associated with testing positive for the *BRCA1/2* gene mutations and elevated familial risk did not differ significantly. The level of distress associated with each of these threats was significantly greater than distress related to being offered testing. Level of distress associated with testing negative for the mutations was significantly less than that related to all other threats. In contrast, for women without a history of breast cancer, level of distress related to testing positive for *BRCA1/2* gene mutations was greater than all other sources of distress. The levels of distress were as follows (greatest to lowest): high familial risk, the possible development of breast cancer, being offered

testing, and testing negative for the gene mutation. Yet, the level of interference from breast cancer worry was not significantly different from level of distress associated with a negative test result and that of being offered testing. Importantly, for both groups of women, results also suggest that elevations in these concerns are not associated with clinically significant distress or interference with daily life.

These findings add to the weight of evidence that genetic testing for *BRCA1/2* mutations may not be as distressing as the literature presents. Instead, testing may be useful as a tool to help women determine their risk for future decisions (e.g., prophylactic surgery). Indeed, testing may help to resolve the chronic stress associated with being a member of a high-risk family and being at personal risk for cancer.

APPENDIX B

Copies of Measures Used in the Current Study

Proband Baseline Questionnaire (Affected and Unaffected Versions)

Proband Baseline Telephone Interview

Proband Interim Questionnaire

Proband Pre-Results Questionnaire (Affected and Unaffected Versions)

Proband 2-Month Post-Results Interview

Proband 6-Month Post-Results Interview

Proband 6-Month Post-Results Questionnaire

Proband 12-Month Post-Results Questionnaire

Spouse Baseline Questionnaire

Spouse 8-Month Post-Results Questionnaire

Sibling Questionnaire

Long-Term Follow-Up Questionnaire (Male and Female Versions)

Telephone Contact Sheet



WOMEN'S HEALTH STUDY

Baseline Questionnaire

Version A

Version A0-August 1997

☐ Less than \$10,000 ☐ \$10,000 to \$19,999 ☐ \$20,000 to \$29,999

- ☐ \$30,000 to \$39,999 ☐ \$40,000 to \$49,999 ☐ \$50,000 to \$59,999
☐ \$60,000 to \$69,999 ☐ Greater than \$69,999

A11. How many people (adults and children) does this income support? _____

B1. When were you first diagnosed with breast cancer? Month _____ Year _____

B2. Have your lymph nodes been affected?
 Yes ☐ No ☐ Do Not Know ☐

B3. Do you currently consider yourself in remission?
 Yes ☐ No ☐ Do Not Know ☐

B4. What treatment(s) have you received for breast cancer?

Chemotherapy	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Radiation	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Surgery	Yes <input type="checkbox"/>	No <input type="checkbox"/>

B5. Have you ever been diagnosed with ovarian cancer? Yes ☐ No ☐
 If yes, when? Month _____ Year _____

B6. Have you ever had any of the following surgical procedures? (Please check all that apply).

B6a. _____ Lumpectomy (Removal of lump from breast)
 If yes, when? Month _____ Year _____

B6b. _____ Oophorectomy (Removal of ovaries)
 If yes, when? Month _____ Year _____

B6c. _____ Unilateral mastectomy (Removal of one breast)
 If yes, when? Month _____ Year _____

B6d. _____ Hysterectomy (Removal of uterus)
 If yes, when? Month _____ Year _____

B6e. _____ Bilateral mastectomy (Removal of both breasts)
 If yes, when? Month _____ Year _____

B7. Before your diagnosis of breast cancer, how likely did you think you were to develop breast cancer, compared to the average woman? (Please circle one)

Much Less Likely				Much More Likely
1	2	3	4	5

B8. Before your diagnosis of breast cancer, how likely did you think you were to develop breast cancer, compared to other women in your family? (Please circle one)

Much Less Likely			Much More Likely
1	2	3	4

B9. Overall, what do you believe your risk is of developing breast cancer again in the near future?
 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

B10. Overall, what do you believe your risk is of developing breast cancer again at some point in your lifetime?
 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

B11. Overall, what do you believe your risk is of developing a metasis (cancer spreading to another site) in the near future?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

B12. Overall, what do you believe your risk is of developing a metasis at some point in your lifetime?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

B13. Overall, what do you believe your risk is of developing cancer unrelated to your breast cancer in the near future?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

B14. Overall, what do you believe your risk is of developing cancer unrelated to your breast cancer at some point in your lifetime?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

B15. A medical test may soon be available that allows some women to learn their genetic risk for developing a form of breast and ovarian cancer that runs in families. Even though you have been diagnosed with breast cancer, would you consider taking the genetic test to learn if your cancer is the type that runs in families? **(Please check one response).**

_____ I will definitely take the test immediately when it becomes available.

_____ I will definitely take the test, but I am not sure if immediately.

_____ I will probably take the test immediately when it becomes available.

_____ I will probably take the test, but not immediately.

_____ I am undecided whether I will take the test.

_____ I will probably not take the test.

_____ I will definitely not take the test.

B16. If you think you will probably or definitely take the test, what are your reasons for doing so? **(Please check all that apply; some may not apply to you).**

_____ To plan for the future.

_____ To reduce the uncertainty.

_____ To know I have to be more careful about doing self examinations and getting regular checkups.

_____ To make decisions about whether to get preventive surgery.

_____ To make decisions about family planning.

_____ To find out the risk that may be transmitted to my children.

_____ Family members want me to get testing.

_____ Other (describe) _____

B17. If you **do not** think you will probably or definitely take the test, what are your reasons for **not** doing so? **(Please check all that apply; some may not apply to you).**

_____ I am happier not knowing.

_____ It would be too upsetting to learn that I am at high risk for breast cancer.

_____ I believe I already know what my risk for breast cancer is.

_____ There would not be much I could do if I found out I was at high risk for breast cancer.

- _____ I do not feel able emotionally to deal with testing.
- _____ Family members do not want me to get testing.
- _____ Risk to my insurance coverage.

SECTION C

For the next questions we are interested in how people close to you respond to you when you are in need of support or reassurance. In answering the questions in the **first column**, please keep in mind a female family member who may be at risk for breast cancer **with whom you are closest**. Answer the questions in the **second column** keeping in mind **your spouse or intimate partner**. *If you do not have a spouse or intimate partner, please leave the second column blank.* For the **third column**, please keep in mind **another family member or friend to whom you are closest**.

	Female Family Member at Risk for Breast Cancer	Spouse/Partner	Another Family Member/ Friend
C1. Was physically present when you needed them.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C2. Told you what he/she did in a similar situation.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C3. Did activities to help you get your mind off things.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C4. Told you that the things you talk about are private--just between the two of you.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C5. Suggested some action you should take.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C6. Comforted you by showing you physical affection.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C7. Listened to you talk about your private feelings.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C8. Agreed that what you want to do is right.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C9. Told you how he/she felt in a similar situation.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C10. Let you know that he/she will always be around if you need assistance.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C11. Gave you feedback on how you were doing without saying it was good or bad.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C12. Pitched in and helped you do things that needed to get done.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C13. Intruded into your personal feelings and concerns.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

	Female Family Member at Risk for Breast Cancer	Spouse/Partner	Another Family Member/ Friend
C14. Gave you unsolicited advice.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C15. Attempted to make unwanted contact.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C16. Discouraged you from discussing your feelings and concerns.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C17. Minimized your worries or concerns.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C18. Rejected you for displaying emotional upset.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C19. Insisted that you remain upbeat and optimistic.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
C20. Let you down when you were counting on him/her.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

C21. Is there anyone in your life with whom you can share your most private feelings without holding back?

☐ Yes ☐ No

C21a. **If you are married or living with a partner**, can you share your most private feelings with this partner without holding back?

☐ Yes ☐ No

SECTION D

D1. Have any of the events listed happened to you in the past six months? **(Check All That Apply)**

- | | |
|--|--|
| <p>a. <input type="checkbox"/> You retired or were fired or laid off from work.-</p> <p>b. <input type="checkbox"/> You were unemployed and looking for work.</p> <p>c. <input type="checkbox"/> Your spouse retired or was fired or laid off from work.</p> <p>d. <input type="checkbox"/> Your spouse was unemployed and looking for work.</p> <p>e. <input type="checkbox"/> You had problems with the police or court.</p> | <p>f. <input type="checkbox"/> You got into serious financial difficulties.</p> <p>g. <input type="checkbox"/> A close family member was seriously ill or injured.</p> <p>h. <input type="checkbox"/> You had a marital separation or divorce.</p> |
|--|--|

- i. ☐ You had serious troubles with relatives or close friends.
- j. ☐ Your spouse had troubles difficulties with relatives or close friends.
- k. ☐ A close family member died.

- l. ☐ A close friend or relative died.
- m. ☐ You were seriously ill or injured.

SECTION E

For each of these statements, please indicate the extent to which you agree or disagree by circling the appropriate number. Try to be as accurate and as honest as you can, and try not to let your answer to one question influence your answers to other questions. There are no right or wrong answers. We are only interested in your opinions.

		Strongly Disagree		Neutral		Strongly Agree
E1.	In uncertain times, I usually expect the best.	1	2	3	4	5
E2.	It's easy for me to relax.	1	2	3	4	5
E3.	If something can go wrong for me, it will.	1	2	3	4	5
E4.	I always look on the bright side of things.	1	2	3	4	5
E5.	I'm always optimistic about my future.	1	2	3	4	5
E6.	I enjoy my friends a lot.	1	2	3	4	5
E7.	It's important for me to keep busy.	1	2	3	4	5
E8.	I hardly ever expect things to go my way.	1	2	3	4	5
E9.	Things never work out the way I want them to	1	2	3	4	5
E10.	I don't get upset too easily.	1	2	3	4	5
E11.	I'm a believer in the idea that "every cloud has a silver lining".	1	2	3	4	5
E12.	I rarely count on good things happening to me.	1	2	3	4	5

PLEASE CONTINUE ON TO NEXT PAGE
SECTION F

Below is a list of words which people might use to describe themselves. You are asked to rate them twice. First, please indicate for each word how well it describes you and second, how much it matters to you using the following scale.

1	2	3	4	5
Extremely	Very much	Somewhat	Not very well	Not at all

		<u>DESCRIBES ME</u>					<u>MATTERS TO ME</u>				
		1	2	3	4	5	1	2	3	4	5
F1.	Involved in family	1	2	3	4	5	1	2	3	4	5
F2.	Aware of being a woman	1	2	3	4	5	1	2	3	4	5
F3.	Involved in paid work	1	2	3	4	5	1	2	3	4	5
F4.	Being a mother	1	2	3	4	5	1	2	3	4	5
F5.	Involved in organization/ volunteer work	1	2	3	4	5	1	2	3	4	5
F6.	Being a grandmother	1	2	3	4	5	1	2	3	4	5
F7.	Physically attractive	1	2	3	4	5	1	2	3	4	5
F8.	Being a wife	1	2	3	4	5	1	2	3	4	5
F9.	Healthy	1	2	3	4	5	1	2	3	4	5
F10.	Being a daughter	1	2	3	4	5	1	2	3	4	5
F11.	Intelligent	1	2	3	4	5	1	2	3	4	5
F12.	Able to cope	1	2	3	4	5	1	2	3	4	5
F13.	Spiritual or religious	1	2	3	4	5	1	2	3	4	5
F14.	Outgoing	1	2	3	4	5	1	2	3	4	5
F15.	Independent	1	2	3	4	5	1	2	3	4	5
F16.	Realistic	1	2	3	4	5	1	2	3	4	5
F17.	Active	1	2	3	4	5	1	2	3	4	5
F18.	Loved	1	2	3	4	5	1	2	3	4	5
F19.	Caring	1	2	3	4	5	1	2	3	4	5

F20.	Depressed	1	2	3	4	5	1	2	3	4	5
------	-----------	---	---	---	---	---	---	---	---	---	---

SECTION G

In the next table, we would like you to first rate how well you think each word will describe you *in the future*, and then, indicate how important it is for you to see yourself this way *in the future*.

1	2	3	4	5
Extremely	Very much	Somewhat	Not very well	Not at all

		<u>WILL DESCRIBE YOU</u>					<u>IMPORTANT FOR YOU TO SEE YOURSELF THIS WAY IN FUTURE</u>				
		1	2	3	4	5	1	2	3	4	5
G1.	Involved in family	1	2	3	4	5	1	2	3	4	5
G2.	Aware of being a woman	1	2	3	4	5	1	2	3	4	5
G3.	Involved in paid work	1	2	3	4	5	1	2	3	4	5
G4.	Being a mother	1	2	3	4	5	1	2	3	4	5
G5.	Involved in organization/volunteer work	1	2	3	4	5	1	2	3	4	5
G6.	Being a grandmother	1	2	3	4	5	1	2	3	4	5
G7.	Physically attractive	1	2	3	4	5	1	2	3	4	5
G8.	Being a wife	1	2	3	4	5	1	2	3	4	5
G9.	Healthy	1	2	3	4	5	1	2	3	4	5
G10.	Being a daughter	1	2	3	4	5	1	2	3	4	5
G11.	Intelligent	1	2	3	4	5	1	2	3	4	5
G12.	Able to cope	1	2	3	4	5	1	2	3	4	5
G13.	Spiritual or religious	1	2	3	4	5	1	2	3	4	5
G14.	Outgoing	1	2	3	4	5	1	2	3	4	5
G15.	Independent	1	2	3	4	5	1	2	3	4	5
G16.	Realistic	1	2	3	4	5	1	2	3	4	5
G17.	Active	1	2	3	4	5	1	2	3	4	5
G18.	Loved	1	2	3	4	5	1	2	3	4	5
G19.	Caring	1	2	3	4	5	1	2	3	4	5
G20.	Depressed	1	2	3	4	5	1	2	3	4	5

SECTION H

The following questions apply to persons who are married or living with a partner. Please complete them if you are. If you are not married or living with a partner, please skip to Section I on page 13.

Most persons have disagreements in their relationships. Please indicate, with check marks, on the following list, the extent of agreement or disagreement experienced between you and your partner **DURING THE PAST MONTH**.

		Always Agree	Almost Always Agree	Occasionally Disagree	Frequently Disagree	Almost Always Disagree	Always Disagree
H1.	Handling family finances						
H2.	Matters of recreation						
H3.	Religious matters						
H4.	Demonstration of affection						
H5.	Friends						
H6.	Sex relations						
H7.	Conventionality (correct or proper behavior)						
H8.	Philosophy of life						
H9.	Ways of dealing with parents or in-laws						
H10.	Aims, goals, and things believed important						
H11.	Amount of time spent together						
H12.	Making major decisions						
H13.	Household tasks						
H14.	Leisure time interests and activities						
H15.	Career decisions						

		All of the time	Most of the time	More often than most	Occasionally	Rarely	Never
H16.	How often do you discuss or have you considered divorce, separation, or terminating your relationship?						
H17.	How often do you or your mate leave the house after a fight?						
H18.	In general, how often do you think that things between you and your partner are going well?						
H19.	Do you confide in your mate?						
H20.	Do you ever regret that you married (or lived together)?						
H21.	How often do you and your partner quarrel?						
H22.	How often do you and your mate "get on each other's nerves?"						

		Every Day	Almost Every Day	Occasionally	Rarely	Never
H23.	Do you kiss your mate?					

		All of Them	Most of Them	Some of Them	Very few of Them	None of Them
H24.	Do you and your mate engage in outside interests together?					

How often would you say the following events occur between you and your mate?

		Never	Less than once a month	About twice a month	About twice a week	Once a day	More Often
H25.	Have a stimulating exchange of ideas.						
H26.	Laugh together.						
H27.	Calmly discuss something.						
H28.	Work together on a project.						

These are some things couples sometimes agree and sometimes disagree upon. Indicate if either item below caused differences of opinions or were problems in your relationship during the past month. **(Check yes or no).**

H29. Being too tired for sex. ☐ Yes ☐ No

H30. Not showing love. ☐ Yes ☐ No

H31. The following scale represents different degrees of happiness in your relationship. The middle point "happy" represents the degree of happiness of most relationships. Please circle the statement which best describes the degree of happiness, all things considered, of your relationship.

Extremely Unhappy	Fairly Unhappy	A Little Unhappy	Happy	Very Happy	Extremely Happy	Perfect
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H32. Please check one of the following statements which best describes how you feel about the **future** of your relationship.

_____ I want desperately for my relationship to succeed, and would go to almost any length to see that it does.

_____ I want very much for my relationship to succeed, and will do all I can to see that it does.

_____ I want very much for my relationship to succeed, and will do my fair share to see that it does.

_____ It would be very nice if my relationship succeeded, but I can't do much more than I am doing now to help it succeed.

_____ It would be nice if it succeeded, but I refuse to do any more than I am doing now to keep the relationship going.

_____ My relationship can never succeed, and there is no more that I can do to keep the relationship going.

PLEASE CONTINUE ON TO NEXT PAGE

SECTION I

I1. In general, would you say your health is:

☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

I2. Compared to one year ago, how would you rate your health in general now?(Check one)

- ☐ Much better now than one year ago
☐ Somewhat better now than one year ago
☐ About the same as one year ago
☐ Somewhat worse now than one year ago
☐ Much worse than one year ago

I3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? *Please mark the appropriate box to indicate your response.*

		<i>YES, limited a lot.</i>	<i>YES, limited a little.</i>	<i>NO, not limited at all.</i>
a.	Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.			
b.	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.			
c.	Lifting or carrying groceries.			
d.	Climbing several flights of stairs.			
e.	Climbing one flight of stairs.			
f.	Bending, kneeling, or stooping.			
g.	Walking more than a mile.			
h.	Walking several blocks.			
i.	Walking one block.			
j.	Bathing or dressing yourself.			

4. **During the past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of your **physical** health?

I4a. Cut down the amount of time you spent on work or other activities.

☐ Yes ☐ No

I4b. Accomplished less than you would like.

☐ Yes ☐ No

I4c. Were limited in the kind of work or other activities.

☐ Yes ☐ No

I4d. Had difficulty performing the work or other activities (for example, it took extra effort).

☐ Yes ☐ No

15. **During the past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of any **emotional** problems (such as feeling depressed or anxious)?

I5a. Cut down the amount of time you spent on work or other activities. ☐ Yes ☐ No

I5b. Accomplished less than you would like. ☐ Yes ☐ No

I5c. Didn't do work or other activities as carefully as usual. ☐ Yes ☐ No

16. **During the past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

☐ Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely

17. How much bodily pain have you had **during the past 4 weeks**?

☐ Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely

18. **During the past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely

19. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the

way you have been feeling. How much of the time **during the past 4 weeks**: *Please mark the appropriate box to indicate your response.*

		All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a.	Did you feel full of pep?						
b.	Have you been a very nervous person?						
c.	Have you felt so down in the dumps that nothing could cheer you up?						
d.	Have you felt calm and peaceful?						
e.	Did you have a lot of energy?						
f.	Have you felt downhearted and blue?						
g.	Have you been a happy person?						
h.	Did you feel tired?						

I10. **During the past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

- ☐ All of the time
 ☐ Most of the time
 ☐ A good bit of the time
 ☐ Some of the time
 ☐ A little of the time
 ☐ None of the time

PLEASE CONTINUE ON TO NEXT PAGE

I11. How **TRUE** or **FALSE** is each of the following statements for you?

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people.					
b. I am as healthy as anybody I know.					
c. I expect my health to get worse.					
d. My health is excellent.					

I12. In the past 6 months, have you had two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun?

I12a. If yes, there was such a two-week period, did your work or relationships suffer?

☐ Yes ☐ No

I12b. If yes, there was such a two-week period, did you get counseling or psychotherapy?

☐ Yes ☐ No

I12c. If there was such a two-week period, did you get medication for this condition?

☐ Yes ☐ No

I13. Are you **currently** receiving counseling or psychotherapy or medication for depression or emotional problems?

☐ Yes ☐ No

PLEASE CONTINUE ON TO NEXT PAGE
SECTION J

J1. How often do you have a drink containing alcohol?

- ☐ Never ☐ Monthly or less ☐ Two to four times a month
☐ Two to three times a week ☐ Four or more times a week

J2. How many drinks containing alcohol do you have on a typical day when you are drinking?

- ☐ 1 or 2 ☐ 3 or 4 ☐ 5 or 6 ☐ 7 to 9 ☐ 10 or more

J3. Have you ever felt you should cut down on your drinking?

- ☐ Yes ☐ No

J4. Have people annoyed you by criticizing your drinking?

- ☐ Yes ☐ No

J5. Have you ever felt bad or guilty about drinking?

- ☐ Yes ☐ No

J6. Have you ever taken a drink first thing in the morning to steady your nerves or get rid of a hangover?

- ☐ Yes ☐ No

PLEASE CONTINUE ON TO NEXT PAGE

Listed Below Are Some Symptoms Of Strain That People Sometimes Have. *Please Read Each One Carefully And Check The Answer Which Best Reflects How Much That Symptom Has Bothered You During the **Past Three Months**.*

	<i>Not at all</i>	<i>A little</i>	<i>Quite a bit</i>	<i>Extremely</i>
K1. Suddenly scared for no reason				
K2. Feeling fearful				
K3. Faintness, dizziness, or weakness				
K4. Nervousness or shakiness inside				
K5. Heart pounding or racing				
K6. Trembling				
K7. Feeling tense or keyed up				
K8. Headaches				
K9. Spells of terror or panic				
K0. Feeling restless, can't sit still				
K11. Feeling low in energy--slowed down				
K12. Blaming yourself for things				
K13. Crying easily				
K14. Loss of sexual interest or pleasure				
K15. Poor appetite				
K16. Difficult falling asleep, staying asleep				
K17. Feeling hopeless about the future				
K18. Feeling blue				
K9. Feeling lonely				
K20. Feeling trapped or caught				
K21. Worrying too much about things				
K22. Feeling no interest in things				
K23. Thoughts of ending your life				
K24. Feeling everything is an effort				
K25. Feelings of worthlessness				

SECTION L

- L1. Vividly imagine that you are afraid of the dentist and have to get some dental work done. Which of the following would you do? Check all of the statements that might apply to you.

_____ I would ask the dentist exactly what he was going to do.

_____ I would take a tranquilizer or have a drink before going.

_____ I would try to think about pleasant memories.

_____ I would want the dentist to tell me when I would feel pain.

_____ I would try to sleep.

_____ I would watch all the dentist's movements and listen for the sound of the drill.

_____ I would watch the flow of water from my mouth to see if it contained blood.

_____ I would do mental puzzles in my mind.

- L2. Vividly imagine that you are being held hostage by a group of armed terrorists in a public building. Which of the following would you do? Check all of the statements that might apply to you.

_____ I would sit by myself and have as many daydreams and fantasies as I could.

_____ I would stay alert and try to keep myself from falling asleep.

_____ I would exchange life stories with the other hostages.

_____ If there was a radio present, I would stay near it and listen to the bulletins about what the police were doing.

_____ I would watch every movement of my captors and keep an eye on their weapons.

_____ I would try to sleep as much as possible.

_____ I would think about how nice it's going to be when I get home.

_____ I would make sure I knew where every possible exit was.

PLEASE CONTINUE ON TO NEXT PAGE

- L3. Vividly imagine that, due to a large drop in sales, it is rumored that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about lay-off's has been made and will be announced in several days. Check all of the statements that might apply to you.

_____ I would talk to my fellow workers to see if they knew anything about what the supervisor's evaluation of me said.

_____ I would review the list of duties for my present job and try to figure out if I had fulfilled them all.

_____ I would go to the movies to take my mind off things.

_____ I would try to remember any arguments or disagreements I might have had with the supervisor that would have lowered his opinion of me.

_____ I would push all thoughts of being laid off out of my mind.

_____ I would tell my spouse that I'd rather not discuss my chances of being laid off.

_____ I would try to think which employees in my department the supervisor might have thought had done the worst job.

_____ I would continue doing my work as if nothing special was happening.

- L4. Vividly imagine that you are on an airplane, 30 minutes from your destination, when the plane unexpectedly goes into a deep dive and then suddenly levels off. After a short time, the pilot announces that nothing is wrong, although the rest of the ride may be rough. You, however, are not convinced that all is well. Check all of the statements that might apply to you.

_____ I would carefully read the information provided about safety features in the plane and make sure I knew where the emergency exits were.

_____ I would make small talk with the passenger beside me.

_____ I would watch the end of the movie, even if I had seen it before.

_____ I would call for the stewardess and ask her exactly what the problem was.

_____ I would order a drink or tranquilizer from the stewardess.

_____ I would listen carefully to the engines for unusual noises and would watch the crew to see if their behavior was out of the ordinary.

_____ I would talk to the passenger beside me about what might be wrong.

_____ I would settle down and read a book or magazine or write a letter.

PLEASE CONTINUE ON TO NEXT PAGE

L5. Please indicate how much you agree with the following statements.

		Strongly Disagree			Strongly Agree	
a.	If you don't have your health, you don't have anything.	1	2	3	4	5
b.	There are many things I care about more than my health.	1	2	3	4	5
c.	Good health is of only minor importance in a happy life.	1	2	3	4	5
d.	There is nothing more important than good health.	1	2	3	4	5

Please indicate the extent to which each of the following items describes your current family.

		Strongly Disagree			Strongly Agree	
M1.	Planning family activities is difficult because we misunderstand each other.	1	2	3	4	5
M2.	In times of crisis we can turn to each other for support.	1	2	3	4	5
M3.	We cannot talk to each other about the sadness we feel.	1	2	3	4	5
M4.	Individuals are accepted for what they are.	1	2	3	4	5
M5.	We avoid discussing our fears and concerns.	1	2	3	4	5
M6.	We can express feelings to each other.	1	2	3	4	5
M7.	There are lots of bad feelings in the family.	1	2	3	4	5
M8.	We feel accepted for what we are.	1	2	3	4	5
M9.	Making decisions is a problem for our family.	1	2	3	4	5
M10.	We are able to make decisions about how to solve problems.	1	2	3	4	5
M11.	We don't get along well together.	1	2	3	4	5
M12.	We confide in each other.	1	2	3	4	5

THANK YOU VERY MUCH.

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Women's Health Study

Telephone Questionnaire

Revised 4/19/96

Introduction/Confidentiality Statement

Hello. My name is _____. I'm calling from the Women's Health Study. Thank you for returning your questionnaire. As we had mentioned, we have some questions about your opinions, experiences, and feelings related to cancer and genetic testing, and about your mood. You may have provided some of this information already, but it is important that we update our records. Before we start, I would like to assure you that your name was picked randomly from the pool of people that had volunteered for the genetic studies. We do not have any new information about your status. I would also like to assure you that this interview is confidential and completely voluntary. If we should come to any questions which you do not want to answer or which do not apply to you, just let me know and we will go on to the next question. For quality control purposes, we would like to tape record this interview if that is all right with you. ...May we begin?

Date_____

Length of IW_____

Length of Edit_____

Interviewer_____

CANCER STATUS:

- 1a. I understand that you (have/have not) been diagnosed with breast cancer.

1. Have Been Diagnosed	5. Have Not
------------------------	-------------

	Breast Cancer Positive
	Ovarian Cancer Positive

IF R INDICATES "HAVE BEEN DIAGNOSED" TO 1a:

- 1b. When were you diagnosed?

DATE: _____ (month/year)

- 1c. On a scale from 1 to 5, with 1 being "not at all distressing" and 5 being "very distressing," how distressed were you by this diagnosis?

Not At All Distressing			Very Distressing	
1	2	3	4	5

- 2a. I understand that you (have/have not) been diagnosed with ovarian cancer.

1. Have Been Diagnosed	5. Have Not
------------------------	-------------

IF R INDICATES "HAVE BEEN DIAGNOSED" TO 2a:

- 2b. When were you diagnosed?

DATE: _____ (month/year)

- 2c. On a scale from 1 to 5, with 1 being "not at all distressing" and 5 being "very distressing," how distressed were you by this diagnosis?

Not At All Distressing			Very Distressing	
1	2	3	4	5

IF R INDICATES "HAVE BEEN DIAGNOSED" TO EITHER 1a OR 2a OR BOTH:

- 2d. Have you ever had a second diagnosis of cancer? E.G. AFTER REMISSION, ETC.

1. Yes	5. No
--------	-------

IF R INDICATES "YES" TO 2d:

2e. When did you receive this second diagnosis?

DATE: _____ (month/year)

2f. On a scale from 1 to 5, with 1 being "not at all distressing" and 5 being "very distressing," how distressed were you by this diagnosis?

Not At All Distressing			Very Distressing	
1	2	3	4	5

IF R INDICATES "YES" or "HAVE BEEN DIAGNOSED" TO 1a, 2a, OR 2d:

2g. Is your cancer currently in remission?

1. Yes	5. No
--------	-------

IF R INDICATES "YES" TO 2g:

2h. How long has your cancer been in remission?

TIME: _____ (months)

2i. On a scale from 1 to 5, how distressing is it to be a member of a family that may be at risk for breast cancer?

Not At All Distressing			Very Distressing	
1	2	3	4	5

A test is now available which allows women in high-risk families to find out if they (personally) have the alteration(s) of a gene (BRCA1) associated with increased risk for breast and ovarian cancer.

2j. On a scale from 1 to 5, how distressing is it to be given the opportunity to be tested for this gene?

Not At All Distressing			Very Distressing	
1	2	3	4	5

2k. On a scale from 1 to 5, 1 being "not at all," and 5 being "very much," to what extent do you welcome the opportunity to be tested?

Not At All			Very Much	
1	2	3	4	5

- 2l. On a scale from 1 to 5, with 1 being "not at all distressing," and 5 being "very distressing," how distressing would it be to have the test and discover that you have the altered gene that is associated with an increased risk for breast and ovarian cancer?

Not At All Distressing			Very Distressing	
1	2	3	4	5

- 2m. Using the same scale, how distressing would it be to have the test and discover that you do not have the altered gene?

Not At All Distressing			Very Distressing	
1	2	3	4	5

FOR QUESTIONS 3-5b, INDICATE THE NUMBER OF RELATIVES AFFECTED BY CANCER - ENTER ZERO FOR NO CANCER DIAGNOSIS IN A CATEGORY

		Mother	Sister(s)	Daughter(s)	First Aunt(s)	Grandmother(s)	First Cousin(s)
3.	Which of your relatives has had breast cancer?						
4.	Which of your relatives has had ovarian cancer?						
5a.	Have any of your relatives died of breast cancer?						
5b.	Have any of your relatives died of ovarian cancer?						

NOT INCLUDING
GREAT-
GRANDMOTHERS

RELATIVES AFFECTED BY CANCER:

REPEAT THIS SECTION (QUESTIONS 0-10) FOR EACH RELATIVE R INDICATES AFFECTED BY CANCER

Now I am going to ask you about your experiences with cancer among your close relatives.

Let's Start with _____ (relationship)

0. Is she from your mother or your father's side of the family?

Mother's	Father's
1	2

1. When was she diagnosed?

DATE: _____ (year)

1a. On a scale from 1 to 5, how distressed were you by her diagnosis?

Not At All Distressed			Very Distressed		Didn't Know IF VOL.
1	2	3	4	5	6

2. Is she alive?

1. Yes	5. No
--------	-------

IF R ANSWERS "NO" TO 2:

2a. Did she die of the cancer or something related to it?
SCORE R's BELIEF

1. Yes	5. No
--------	-------

IF R ANSWERS "YES" To 2a:

2b. When did she die?

DATE: _____ (year)

2c. How old was she when she died?

AGE: _____ (years)

2d. How old were you when she died?

AGE: _____ (years)

2e. On a scale from 1 to 5, how distressed were you by this news?

Not At All Distressed			Very Distressed	
1	2	3	4	5

Didn't Know IF VOL.
6

3. What treatment did she receive? SCORE EACH SURGERY SEPARATELY

Treatment:	1. Yes	5. No
A. Lumpectomy		
B. Unilateral Mastectomy		
C. Bilateral Mastectomy		
D. Oophorectomy (ovaries removed)		
E. Hysterectomy		
F. Chemotherapy		
G. Radiation		
H. Hormonal Therapy		
I. Immunotherapy		
J. Don't Know		
K. Other		
L. None		

IF BOTH BREASTS REMOVED IN
TWO SEPARATE SURGERIES
SCORE YES FOR UNILATERAL
AND YES FOR BILATERAL

On a scale of 1 to 5, with 1 being "not at all" and 5 being "very much,"

		Not At All					Very Much	Didn't Know IF VOL.
4.	At the time of the illness, how (emotionally) close were you to your (relative)?	1	2	3	4	5		6

On a scale of 1 to 5, with 1 being "not at all" and 5 being "very much",

5. At the time of her illness, how aware were you of the following aspects of your (relative's) condition?

	Not at All				Very Much	Didn't Know If Vol
A. Diagnosis	1	2	3	4	5	6
B. Course of illness	1	2	3	4	5	6
C. Prognosis (what could be expected)	1	2	3	4	5	6
D. Her pain or suffering	1	2	3	4	5	6
E. Side effects of treatment	1	2	3	4	5	6
F. Impairment (not being able to do what she once did) and disruption of her life	1	2	3	4	5	6
G. How involved were you in the treatment and care of your (relative)?	1	2	3	4	5	6

6. At the time of her illness, did you help care for her in any of the following ways?

	1. Yes	5. No
A. Accompanied to appointments		
B. Visited at hospital		
C. Did chores for her		
D. Provided comfort and emotional support		

On a scale of 1 to 5, with 1 being "not at all" and 5 being "very much,"

	Not At All				Very Much	Didn't Know IF VOL.
7. At that time, to what extent did you talk with her about her experience?	1	2	3	4	5	6
8. At that time, how upsetting was her experience with cancer for you? [OVERALL]	1	2	3	4	5	6

	Much More Distant	A Little More Distant	No Change	A Little Closer	A Lot Closer
9. At that time, how did your (relative's) illness affect your relationship with other family members? Did it make you...[READ OPTIONS]	1	2	3	4	5

On a scale of 1 to 5, with 1 being "not at all" and 5 being "very much,"

	Not At All				Very Much	Didn't Know IF VOL.
10. How much has your experience with your (relative) affected the way you think about your own risk for cancer and options for dealing with it? [CURRENTLY]	1	2	3	4	5	6

REPEAT QUESTIONS 0-10 (STARTING ON PAGE 5) FOR ANY ADDITIONAL RELATIVES

11. Now I'd like to find out how you keep up with new information about breast cancer (including prevention, detection, and treatment). I'm going to read you a list of sources; On a scale from 1 to 5, with 1 being "not at all" and 5 being "very much," how much do you rely on... REPEAT AS NECESSARY

	Not At All				Very Much
a. Your OB/GYN	1	2	3	4	5
b. Your family physician	1	2	3	4	5
c. Another physician (Specialty_____)	1	2	3	4	5
d. Family Members [WHO GAVE INFO]	1	2	3	4	5
e. Friends [WHO GAVE INFO]	1	2	3	4	5
f. Newspapers, television, and radio	1	2	3	4	5
g. Popular women's magazines	1	2	3	4	5
h. Other (specify_____)	1	2	3	4	5

READ OPTIONS

		Not At All	A Little	Somewhat	A Great Deal
12.	How much do you watch for new information in the media (newspaper, magazines, television, radio)?	1	2	3	4
13.	How much do you try to avoid this information in the media?	1	2	3	4
14.	How much confidence do you have in the accuracy of such information in the media?	1	2	3	4

15bi. Are you aware of the gene (BRCA1) associated with increased risk for early onset breast cancer?

1. Yes	5. No
--------	-------

IF R ANSWERS "YES" TO 15b:

	Hopeful	Relieved	Anxious or Fearful	Depressed
15c. Which of the following best describes how you felt when you heard about the discovery of this gene? READ OPTIONS - R MAY CHOOSE ONLY ONE	1	2	3	4

IF R ANSWERS "YES" TO 15b:

	Not At All	A Little	Somewhat	A Great Deal
15d. How much did you discuss this development with your mother and/or your sisters? READ OPTIONS	1	2	3	4
15e. IF R IS MARRIED/PARTNERED: How much have you discussed this development with your (spouse/partner)? READ OPTIONS	1	2	3	4
15f. IF R HAS CHILDREN: How much have you discussed this development with your children? READ OPTIONS	1	2	3	4

15g. IF R IS CANCER POSITIVE:

Women who are living with breast cancer report various levels of distress.
How often do you feel distressed about living with breast cancer?

IF R IS CANCER NEGATIVE:

Women who are at risk for breast cancer report various levels of distress.
How often do you feel distressed about your risk for breast cancer?

READ OPTIONS

Never	Rarely	Sometimes	Often
1	2	3	4

15h. Thinking about your family's risk for breast cancer and your own diagnosis/risk, what has been the most distressing part?

15i. On a scale from 1 to 5, how distressing is this?

Not At All Distressing			Very Distressing	
1	2	3	4	5

FOR WOMEN WITH LIVING SISTERS:

SKIP IF R HAS NO LIVING SISTERS

Now I'm going to ask some questions about your relationship with your sisters.

16a. IF R IS CANCER POSITIVE:

How often do you discuss living with breast cancer with your sisters?

IF R IS CANCER NEGATIVE:

How often do you discuss your risk for breast cancer with your sisters?

READ OPTIONS

Never	Rarely	Sometimes	Often
1	2	3	4

IF R ANSWERS "NEVER" TO 16a, DO NOT ASK 16b-d

16b. When you have these discussions, who generally initiates them?

You	Your Sisters	Equally [IF VOLUNTEERED]
1	2	3

16c. How satisfied are you with these discussions?

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

16d. What is helpful to you when talking with your sisters about your risk for breast cancer?
SCORE ALL THAT APPLY - R CAN CHOOSE MORE THAN ONE - SCORE WHAT IS CURRENTLY HELPFUL, NOT WHAT THEY BELIEVE MIGHT BE HELPFUL

	1. Yes	5. No
1. Receiving new information.		
2. The opportunity to express your feelings.		
3. Receiving comfort or being taken care of.		
4. Feeling understood.		
5. Knowing you are not alone.		

16e. Overall, how important is your sister's opinion in your decision whether or not to be tested for the breast cancer gene?

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

- 16f. In making decisions about what to do to reduce your risk of breast cancer in the future, how important is your sister's opinion?
IF R INSISTS THAT THERE ARE NO MORE DECISIONS TO BE MADE, CODE 1

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

- 16g. Considering **only the positive feelings** you have toward your sisters, and **ignoring the negative ones**, please rate how positive these feelings are. Use a scale of 1 to 10, with 1 being "not at all positive" and 10 being "extremely positive." SCORE GENERAL FEELING TOWARD PERSON, NOT JUST REGARDING CANCER

Not At All Positive							Extremely Positive		
1	2	3	4	5	6	7	8	9	10

- 16h. Considering **only the negative feelings** you have toward your sisters, and **ignoring the positive ones**, please rate how negative these feelings are. Use a scale of 1 to 10, with 1 being "not at all negative" and 10 being "extremely negative." SCORE GENERAL FEELING TOWARD PERSON, NOT JUST REGARDING CANCER

Not At All Negative							Extremely Negative		
1	2	3	4	5	6	7	8	9	10

FOR WOMEN WITH LIVING MOTHERS:
SKIP IF R's MOTHER IS NOT LIVING

Now I am going to ask some questions about your relationship with your mother.

- 17a. IF R IS CANCER POSITIVE:
How often do you discuss living with breast cancer with your mother?

IF R IS CANCER NEGATIVE:
How often do you discuss your risk for breast cancer with your mother?

READ OPTIONS

Never	Rarely	Sometimes	Often
1	2	3	4

IF R ANSWERS "NEVER" TO 17a, DO NOT ASK 17b-d

17b. When you have these discussions, who generally initiates them?

You	Your Mother	Equally [IF VOLUNTEERED]
1	2	3

17c. How satisfied are you with these discussions?

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

17d. What is helpful to you when talking with your mother about your risk for breast cancer?
SCORE ALL THAT APPLY - R CAN CHOOSE MORE THAN ONE - SCORE WHAT IS CURRENTLY HELPFUL, NOT WHAT THEY BELIEVE MIGHT BE HELPFUL

	1. Yes	5. No
1. Receiving new information.		
2. The opportunity to express your feelings.		
3. Receiving comfort or being taken care of.		
4. Feeling understood.		
5. Knowing you are not alone.		

17e. Overall, how important is your mother's opinion in your decision whether or not to be tested for the breast cancer gene?

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

- 17f. In making decisions about what to do to reduce your risk of breast cancer in the future, how important is your mother's opinion?
IF R INSISTS THAT THERE ARE NO MORE DECISIONS TO BE MADE, CODE 1

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

- 17g. Considering **only the positive feelings** you have toward your mother, and **ignoring the negative ones**, please rate how positive these feelings are. Use a scale of 1 to 10, with 1 being "not at all positive" and 10 being "extremely positive." SCORE GENERAL FEELING TOWARD PERSON, NOT JUST REGARDING CANCER

Not At All Positive					Extremely Positive				
1	2	3	4	5	6	7	8	9	10

- 17h. Considering **only the negative feelings** you have toward your mother, and **ignoring the positive ones**, please rate how negative these feelings are. Use a scale of 1 to 10, with 1 being "not at all negative" and 10 being "extremely negative." SCORE GENERAL FEELING TOWARD PERSON, NOT JUST REGARDING CANCER

Not At All Negative					Extremely Negative				
1	2	3	4	5	6	7	8	9	10

FOR WOMEN WHO ARE MARRIED OR LIVING WITH A PARTNER:
SKIP IF R IS NOT MARRIED/PARTNERED

Now I am going to ask you some questions about your relationship with your (husband/partner).

- 18a. IF R IS CANCER POSITIVE:
How often do you discuss living with breast cancer with your husband/partner?

IF R IS CANCER NEGATIVE:
How often do you discuss your risk for breast cancer with your husband/partner?

READ OPTIONS

Never	Rarely	Sometimes	Often
1	2	3	4

IF R ANSWERS "NEVER" TO 18a, DO NOT ASK 18b-d

18b. When you have these discussions, who generally initiates them?

You	Your Husband/ Partner	Equally [IF VOLUNTEERED]
1	2	3

18c. How satisfied are you with these discussions?

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

18d. What is helpful to you when talking with your husband/partner about your risk for breast cancer?
SCORE ALL THAT APPLY - R CAN CHOOSE MORE THAN ONE - SCORE WHAT IS CURRENTLY HELPFUL, NOT WHAT THEY BELIEVE MIGHT BE HELPFUL

	1. Yes	5. No
1. Receiving new information.		
2. The opportunity to express your feelings.		
3. Receiving comfort or being taken care of.		
4. Feeling understood.		
5. Knowing you are not alone.		

18e. Overall, how important is your husband/partner's opinion in your decision whether or not to be tested for the breast cancer gene?

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

- 18f. In making decisions about what to do to reduce your risk of breast cancer in the future, how important is your (husband's/partner's) opinion?
IF R INSISTS THAT THERE ARE NO MORE DECISIONS TO BE MADE, CODE 1

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

- 18g. Considering **only the positive feelings** you have toward your husband/partner, and **ignoring the negative ones**, please rate how positive these feelings are. Use a scale of 1 to 10, with 1 being "not at all positive" and 10 being "extremely positive." SCORE GENERAL FEELING TOWARD PERSON, NOT JUST REGARDING CANCER

Not At All Positive					Extremely Positive				
1	2	3	4	5	6	7	8	9	10

- 18h. Considering **only the negative feelings** you have toward your husband/partner, and **ignoring the positive ones**, please rate how negative these feelings are. Use a scale of 1 to 10, with 1 being "not at all negative" and 10 being "extremely negative." SCORE GENERAL FEELING TOWARD PERSON, NOT JUST REGARDING CANCER

Not At All Negative					Extremely Negative				
1	2	3	4	5	6	7	8	9	10

FOR WOMEN WITH LIVING DAUGHTER/S:
SKIP IF R HAS NO LIVING DAUGHTER/S

Now I am going to ask you some questions about your relationship with your daughter/s.

- 19i. What are the ages of your daughters?

_____	_____	_____
_____	_____	_____
_____	_____	_____

- 19ii. In general, do you discuss family history and risk for breast cancer with your daughter/s?

1. Yes	5. No
--------	-------

- 19e. Overall, how important is/are your daughters' opinion in your decision whether or not to be tested for the breast cancer gene?

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

- 19f. In making decisions about what to do to reduce your risk of breast cancer in the future, how important is/are your daughter's opinion/s?
IF R INSISTS THAT THERE ARE NO MORE DECISIONS TO BE MADE, CODE 1

READ OPTIONS

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

- 19g. Considering **only the positive feelings** you have toward your daughters, and **ignoring the negative ones**, please rate how positive these feelings are. Use a scale of 1 to 10, with 1 being "not at all positive" and 10 being "extremely positive." SCORE GENERAL FEELING TOWARD PERSON, NOT JUST REGARDING CANCER

Not At All Positive					Extremely Positive				
1	2	3	4	5	6	7	8	9	10

- 19h. Considering **only the negative feelings** you have toward your daughters, and **ignoring the positive ones**, please rate how negative these feelings are. Use a scale of 1 to 10, with 1 being "not at all negative" and 10 being "extremely negative." SCORE GENERAL FEELING TOWARD PERSON, NOT JUST REGARDING CANCER

Not At All Negative					Extremely Negative				
1	2	3	4	5	6	7	8	9	10

FOR WOMEN WITH CHILDREN:
SKIP IF R HAS NO CHILDREN

- 19iii. If you should choose to obtain genetic testing, do you intend to inform your children of the results?

1. Yes	5. No	7. Undecided [IF VOLUNTEERED]
--------	-------	----------------------------------

FOR ALL WOMEN:

20. If you were to find that you were a carrier for BRCA1, the gene for increased risk of breast cancer, what options would you consider?

[DONE]



WOMEN'S HEALTH STUDY

Interim Questionnaire - 1999

TODAY'S DATE _____

ID _____

INTERIM QUESTIONNAIRE - A

GENETIC TESTING-SECTION 1

1. Have you contributed a blood or tissue sample to the GENETIC TESTING portion of the research project?

☐ Yes ☐ No

B21.

2. Has any member of your family contributed a blood or tissue sample to the GENETIC TESTING portion of the research project?

☐ Yes ☐ No ☐ I Don't Know

B22.

3. Have you or any family members received notification that genetic results are available?

B23.

There Has Been No Notification	Results Are Available	Results Are NOT YET Available	Results will NEVER BE Available, I am Not Eligible

4. Have **you** received results of genetic testing for breast or ovarian cancer?

☐ Yes ☐ No (Skip to Question 5)

4a. When did this occur? _____(mo/yr)

4b. What was the source of this information?

☐ University of Pennsylvania ☐ Independent Testing ☐ Other: _____

4c. What were the results? (Optional)

5. Has **any family member** received results of genetic testing for breast or ovarian cancer?

☐ Yes ☐ No (Skip to Next Section) ☐ Don't Know (Skip to Next Section)

5a. When did this occur? _____(mo/yr)

5b. What was the source of this information?

☐ University of Pennsylvania ☐ Independent Testing ☐ Other: _____

5c. What were the results? (Optional)

5d. Can you infer your genetic results from your relative's results (i.e., Have you been able to figure out whether you are positive or negative for the gene that conveys higher risk for breast cancer with this information?)

☐ Yes ☐ No ☐ Don't Know

PERSONAL ATTITUDES SECTION

1. For each of these statements, please indicate the extent to which you agree or disagree by circling the appropriate number. There are no right or wrong answers. We are only interested in your opinions.

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>		
a.	If you don't have your health, you don't have anything.	1	2	3	4	5	L5a.
b.	There are many things I care about more than my health.	1	2	3	4	5	L5b.
c.	Good health is of only minor importance in a happy life.	1	2	3	4	5	L5c.
d.	There is nothing more important than good health.	1	2	3	4	5	L5d.
e.	In uncertain times, I usually expect the best.	1	2	3	4	5	E1.
f.	It's easy for me to relax.	1	2	3	4	5	E2.
g.	If something can go wrong for me, it will.	1	2	3	4	5	E3.
h.	I always look on the bright side of things.	1	2	3	4	5	E4.
i.	I'm always optimistic about my future.	1	2	3	4	5	E5.
j.	I enjoy my friends a lot.	1	2	3	4	5	E6.
k.	It's important for me to keep busy.	1	2	3	4	5	E7.
l.	I hardly ever expect things to go my way.	1	2	3	4	5	E8.
m.	Things never work out the way I want them to.	1	2	3	4	5	E9.
n.	I don't get upset too easily.	1	2	3	4	5	E10.
o.	I'm a believer in the idea that "every cloud has a silver lining."	1	2	3	4	5	E11.
p.	I rarely count on good things happening to me.	1	2	3	4	5	E12.

GENETIC TESTING-SECTION 2

1. A medical test may soon be available that allows some women to learn their genetic risk for developing a form of breast and ovarian cancer that runs in families. Even though you have been diagnosed with breast cancer, would you consider taking the genetic test to learn if your cancer is the type that runs in families?

(Please check one response).

B15.

- (1). _____ I will definitely take the test immediately when it becomes available.
 (2). _____ I will definitely take the test, but I am not sure if immediately.
 (3). _____ I will probably take the test immediately when it becomes available.
 (4). _____ I will probably take the test, but not immediately.
 (5). _____ I am undecided whether I will take the test
 (6). _____ I will probably not take the test.
 (7). _____ I will definitely not take the test.

2. On the following scale, indicate how distressing it is for you to know that you may be at increased risk for breast cancer because of your family history?

B66.

Not At All Distressing				Very Distressing
1	2	3	4	5

3. How distressing it is to be given the opportunity to be tested for the BRCA-1 gene, the altered gene associated with increased risk for breast cancer?

B67.

Not At All Distressing				Very Distressing
1	2	3	4	5

4. How distressed do you expect to be when you actually get tested for the BRCA-1 gene (before you receive results)?

B68.

Not At All Distressed				Very Distressed
1	2	3	4	5

5. How distressed would you be if you took the test and found that you **had** the BRCA-1 gene?

B69.

Not At All Distressed				Very Distressed
1	2	3	4	5

6. How distressed would you be if you took the test and found that you **did not have** the BRCA-1 gene? B70.

Not At All Distressed				Very Distressed
1	2	3	4	5

7. Overall, to what extent do you welcome the opportunity to be tested for the BRCA-1 gene? B71.

Not At All				Very Much So
1	2	3	4	5

		Not At All					All The Time
8.	How often do you worry about again developing breast cancer?	1	2	3	4	5	B27.
9.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B28.
10.	How often do you worry about having the altered gene carrying risk for breast cancer ?	1	2	3	4	5	B29.
11.	To what extent do these worries you have about having this altered gene interfere with your every day life?	1	2	3	4	5	B30.

12. Before your diagnosis of breast cancer, how likely did you think you were to develop breast cancer, compared to other women? **(Please circle one)** B7.

Much Less Likely			Much More Likely	
1	2	3	4	5

13. When was the last time you had a mammography? B32.

_____Month _____Year (-8) ☐ This question does not apply because of surgery.

14. How many times have you conducted a breast self-examinations (BSE) in the past six months? B33.

_____times (-8) ☐ This question does not apply because of surgery.

22. Answer the following question only if you have (biological) daughters.

☐ Does Not Apply
(Skip to Next Section, Life Events)

B41.

		<u>Have been affected by being at high risk for breast cancer</u>					<u>Would be affected by the results of genetic testing</u>					
a.	Plans for your daughter's future	1	2	3	4	5	1	2	3	4	5	B42: B42

LIFE EVENTS SECTION

1. Have any of the following events happened to you in the past six months?
(Check All That Apply)

D1(a-m)

- | | |
|--|---|
| a. <input type="checkbox"/> You retired, were fired, or laid off from work. | g. <input type="checkbox"/> A close family member was seriously ill or injured. |
| b. <input type="checkbox"/> You were unemployed and looking for work. | h. <input type="checkbox"/> You had a marital separation or divorce. |
| c. <input type="checkbox"/> Your spouse retired, was fired, or laid off from work. | i. <input type="checkbox"/> You had serious troubles with relatives or close friends. |
| d. <input type="checkbox"/> Your spouse was unemployed and looking for work. | j. <input type="checkbox"/> Your spouse had troubles or difficulties with relatives or close friends. |
| e. <input type="checkbox"/> You had problems with the police or court. | k. <input type="checkbox"/> A close family member died. |
| f. <input type="checkbox"/> You got into serious financial difficulties. | l. <input type="checkbox"/> A close friend or relative died. |
| | m. <input type="checkbox"/> You were seriously ill or injured. |

MARRIAGE SECTION

The following questions apply to persons who are married or living with a partner. If you are not married or living with a partner, check the appropriate box and please skip to the Next Section, MOOD.

Not married or living with a partner ☐

Ha.

Most persons have disagreements in their relationships. Please check the appropriate box to indicate the extent of agreement or disagreement experienced between you and your partner **DURING THE PAST MONTH**, regarding.

		<i>Always Agree</i>	<i>Almost Always Agree</i>	<i>Occasionally Disagree</i>	<i>Frequently Disagree</i>	<i>Almost Always Disagree</i>	<i>Always Disagree</i>	
1.	Religious matters	6	5	4	3	2	1	H3.
2.	Demonstration of affection	6	5	4	3	2	1	H4.
3.	Sex relations	6	5	4	3	2	1	H6.
4.	Conventionality (correct or proper behavior)	6	5	4	3	2	1	H7.
5.	Making major decisions	6	5	4	3	2	1	H12.
6.	Career decisions	6	5	4	3	2	1	H15.

		<i>All of the time</i>	<i>Most of the time</i>	<i>More often than most</i>	<i>Occasionally</i>	<i>Rarely</i>	<i>Never</i>	
7.	How often do you discuss or have you considered divorce, separation, or terminating your relationship?	1	2	3	4	5	6	H16.
8.	Do you ever regret that you married (or are living together)?	1	2	3	4	5	6	H20.
9.	How often do you and your husband/partner quarrel?	1	2	3	4	5	6	H21.
10.	How often do you and your husband/partner "get on each other's nerves?"	1	2	3	4	5	6	H22.

		<i>All of Them</i>	<i>Most of Them</i>	<i>Some of Them</i>	<i>Very few of Them</i>	<i>None of Them</i>
11.	Do you and your husband/partner engage in outside interests together?	5	4	3	2	1

H24.

How often would you say the following events occur between you and your husband/partner?

		<i>Never</i>	<i>Less than once a month</i>	<i>About twice a month</i>	<i>About twice a week</i>	<i>Once a day</i>	<i>More Often</i>
12.	Have a stimulating exchange of ideas	1	2	3	4	5	6
13.	Calmly discuss something	1	2	3	4	5	6
14.	Work together on a project	1	2	3	4	5	6

H25.

H27.

H28.

15. Considering **only the positive feelings** you have toward your husband/partner, and **ignoring the negative ones**, please rate how positive these feelings are:

H33.

Not At All Positive					Extremely Positive				
1	2	3	4	5	6	7	8	9	10

16. Considering **only the negative feelings** you have toward your husband/partner, and **ignoring the positive ones**, please rate how negative these feelings are:

H34.

Not At All Negative					Extremely Negative				
1	2	3	4	5	6	7	8	9	10

17. The following questions concern your husband's involvement in your health care.

		Never Very Often					
a.	How often does your husband/partner go with you to your appointments with doctors?	1	2	3	4	5	H35a.
b.	How often does your husband/partner talk with your doctor or other medical personnel about your risk for breast cancer?	1	2	3	4	5	H35b.
c.	How often does your husband/partner keep track of what you need to do about your risk for breast cancer?	1	2	3	4	5	H35c.
d.	How often does your husband/partner change his activities to assist you in your health care?	1	2	3	4	5	H35d.

18. Has your husband/partner attended individual, family or group sessions to become informed about your risk for breast cancer and what can be done? H36.

(1) Yes ☐ (5) No ☐

19. How much contact has your husband/partner had with medical personnel concerning your risk for breast cancer. H37.

Very Little or None A lot

1 2 3 4 5 6 7

20. Do you feel your husband/partner is adequately informed concerning your risk for breast cancer and what can be done about it? H38.

Not at All Very Much

1 2 3 4 5 6 7

21. To what extent are you satisfied with your husband/partner's involvement in your health care? H39.

Not at All Very Much

1 2 3 4 5 6 7

MOOD SECTION

1. Have you **ever in your lifetime** had two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun? I14
- (1) ☐ Yes (5) ☐ No (Skip to Question 2)
- 1a. If there was such a two-week period, did your work or relationships suffer? I14a.
- (1) ☐ Yes (5) ☐ No
- 1b. If there was such a two-week period, did you get counseling or psychotherapy? I14b.
- (1) ☐ Yes (5) ☐ No
- 1c. If there was such a two-week period, did you get medication for this condition? I14c.
- (1) ☐ Yes (5) ☐ No
2. In the **past 6 months**, have you had two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun? I12.
- (1) ☐ Yes (5) ☐ No (Skip to Question 3)
- 2a. If there was such a two-week period in **the past 6 months**, did your work or relationships suffer? I12a.
- (1) ☐ Yes (5) ☐ No
- 2b. If there was such a two-week period in **the past 6 months**, did you get counseling or psychotherapy? I12b.
- (1) ☐ Yes (5) ☐ No
- 2c. If there was such a two-week period in **the past 6 months**, did you get medication for this condition? I12c.
- (1) ☐ Yes (5) ☐ No
3. Are you **currently** receiving counseling, psychotherapy or medication for depression or emotional problems? I13.
- (1) ☐ Yes (5) ☐ No

Symtoms of Strain Section

LISTED BELOW ARE SOME SYMPTOMS OF STRAIN THAT PEOPLE SOMETIMES HAVE. *Please Read Each One Carefully And Check The Answer Which Best Reflects How Much That Symptom Has Bothered You During the **Past Three Months**.*

		<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Extremely</u>	
1.	Suddenly scared for no reason	1	2	3	4	K1.
2.	Feeling fearful	1	2	3	4	K2.
3.	Faintness, dizziness, or weakness	1	2	3	4	K3.
4.	Nervousness or shakiness inside	1	2	3	4	K4.
5.	Heart pounding or racing	1	2	3	4	K5.
6.	Trembling	1	2	3	4	K6.
7.	Feeling tense or keyed up	1	2	3	4	K7.
8.	Headaches	1	2	3	4	K8.
9.	Spells of terror or panic	1	2	3	4	K9.
10.	Feeling restless, can't sit still	1	2	3	4	K10.
11.	Feeling low in energy--slowed down	1	2	3	4	K11.
12.	Blaming yourself for things	1	2	3	4	K12.
13.	Crying easily	1	2	3	4	K13.
14.	Loss of sexual interest or pleasure	1	2	3	4	K14.
15.	Poor appetite	1	2	3	4	K15.
16.	Difficulty falling asleep, staying asleep	1	2	3	4	K16.
17.	Feeling hopeless about the future	1	2	3	4	K17.
18.	Feeling blue	1	2	3	4	K18.
19.	Feeling lonely	1	2	3	4	K19.
20.	Feeling trapped or caught	1	2	3	4	K20.
21.	Worrying too much about things	1	2	3	4	K21.
22.	Feeling no interest in things	1	2	3	4	K22.
23.	Thoughts of ending your life	1	2	3	4	K23.
24.	Feeling everything is an effort	1	2	3	4	K24.
25.	Feelings of worthlessness	1	2	3	4	K25.

COPING SECTION

1. Sometimes people can find unexpected benefits in difficulties. We are interested in the ways in which you might have made positive use of your risk for breast cancer. For each of the statements below, indicate the degree to which your life is affected positively by your risk of breast cancer.

		<i>Not At All</i>	<i>A Very Small Degree</i>	<i>A Small Degree</i>	<i>A Moderate Degree</i>	<i>A Great Degree</i>	<i>A Very Great Degree</i>	
a.	My priorities about what is important in life.	1	2	3	4	5	6	L6a.
b.	I'm more likely to try to change things which need changing.	1	2	3	4	5	6	L6b.
c.	An appreciation for the value of my own life.	1	2	3	4	5	6	L6c.
d.	A feeling of self-reliance.	1	2	3	4	5	6	L6d.
e.	A better understanding of spiritual matters.	1	2	3	4	5	6	L6e.
f.	Knowing that I can count on people in times of troubles.	1	2	3	4	5	6	L6f.
g.	A sense of closeness with others.	1	2	3	4	5	6	L6g.
h.	Knowing I can handle difficulties.	1	2	3	4	5	6	L6h.
i.	A willingness to express my emotions.	1	2	3	4	5	6	L6i.
j.	Being able to accept the way things work out.	1	2	3	4	5	6	L6j.
k.	Appreciating each day.	1	2	3	4	5	6	L6k.
l.	Having compassion for others.	1	2	3	4	5	6	L6l.
m.	I'm able to do better things with my life.	1	2	3	4	5	6	L6m.
n.	New opportunities are available which wouldn't have been otherwise.	1	2	3	4	5	6	L6n.

2. This set of questions deals with ways you've been coping with the stress in your life that comes with being at risk for breast cancer. There are many ways people try to deal with problems. Obviously, different people deal with things in different ways, but we are interested in how you've tried to deal with it. Each item says something about a particular way of coping. We want to know *to what extent* you've been doing what the item says, how *much* or how *frequently*. Don't answer on the basis of whether it seems to be working but just whether or not you're doing it. Use these response choices below and try not to let one answer influence another. Make your answers as true FOR YOU as you can.

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>	
a.	I've been turning to work or other activities to take my mind off things.	1	2	3	4	L7a.
b.	I've been concentrating my efforts on doing something about my situation.	1	2	3	4	L7b.
c.	I've been saying to myself "this isn't possible."	1	2	3	4	L7c.
d.	I've been using alcohol or other drugs to make myself feel better.	1	2	3	4	L7d.
e.	I've been getting emotional support from others.	1	2	3	4	L7e.
f.	I've been giving up trying to deal with it.	1	2	3	4	L7f.
g.	I've been taking action to try to make the situation better.	1	2	3	4	L7g.
h.	I've been refusing to believe that it is possible that I have an altered gene.	1	2	3	4	L7h.
i.	I've been saying things to let my unpleasant feelings escape.	1	2	3	4	L7i.
j.	I've been using alcohol or other drugs to help me get through it.	1	2	3	4	L7j.
k.	I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4	L7k.
l.	I've been trying to come up with a strategy about what to do.	1	2	3	4	L7l.
m.	I've been getting comfort and understanding from someone.	1	2	3	4	L7m.

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>	
n.	I've been giving up the attempt to cope.	1	2	3	4	L7n.
o.	I've been accepting the possibility that I might have an altered gene.	1	2	3	4	L7o.
p.	I've been expressing my negative feelings.	1	2	3	4	L7p.
q.	I've been trying to find comfort in my religion or spiritual beliefs.	1	2	3	4	L7q.
r.	I've been learning to live with the possibility that I might have the gene.	1	2	3	4	L7r.
s.	I've been thinking hard about what steps to take.	1	2	3	4	L7s.
t.	I've been praying or meditating.	1	2	3	4	L7t.
u.	I've been making fun of the situation.	1	2	3	4	L7u.

3. The following items are to be answered only by those women who are married or living with a partner.

(-8) ☐ Not married or living with a partner

L8.

(Skip to Last Section on page 15, Background Data)

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>	
a.	I've been denying or hiding my anger around my husband/partner.	1	2	3	4	L8a.
b.	I've been denying or hiding my worries around my husband/partner.	1	2	3	4	L8b.
c.	I've been avoiding talking about my problems around my husband/partner.	1	2	3	4	L8c.
d.	I've acted more positive around my husband/partner than I feel.	1	2	3	4	L8d.

BACKGROUND DATA

These are a few questions about your religious background, that we forgot to ask on the original questionnaire.

1. Religion: Catholic (1) ☐ Protestant (4) ☐ A 3.
Jewish (2) ☐ Buddhist (5) ☐
Muslim (3) ☐ Other (6) ☐
None (7) ☐

- 1a. How often do you attend religious services? A 3a.
(1) (5)
☐ Less Often Than Once a Month ☐ A Few Times A Month or More

- 1b. How important are religious and spiritual beliefs in your life? A 3b.
Not at All 1 2 3 4 Very Important 5

Once Again, We thank you for all of your valued participation in this study.

TODAY'S DATE _____

ID _____

PRE-RESULTS QUESTIONNAIRE - A

You may notice that some of these questions were asked in previous questionnaires, but many of the questions are new. We are asking them again because we are interested in feelings and attitudes which may change over time.
THANK YOU VERY MUCH!

GENETIC TESTING-SECTION 1

1. Have you met with anyone to have genetic counseling? **B24.**
(1) ☐ Yes (5) ☐ No
2. Has any member of your family met with someone to have genetic counseling ? **B25.**
(1) ☐ Yes (5) ☐ No
3. As the opportunity to get testing has approached, has your interest in getting results changed? **B74.**
- | | | | | |
|-------------------------------------|------------------------------------|---------------------------|------------------------------------|-------------------------------------|
| Decreased
Very Much
1 | Decreased
Slightly
2 | No
Change
3 | Increased
Slightly
4 | Increased
Very Much
5 |
|-------------------------------------|------------------------------------|---------------------------|------------------------------------|-------------------------------------|
4. At this time, what is your decision regarding receiving your genetic results? **B112.**
(1) ☐ I will probably or definitely receive my results now, as soon as they are offered.
(Skip to Question 5)
(3) ☐ I do not intend to receive my results now, but may do so later. (Skip to Question 6)
(5) ☐ I do not intend to receive my results now or in the future. (Skip to Question 7)
5. If you will probably or definitely obtain your results **now** , as soon as they are being offered to you, what are your reasons for doing so? **B113.**
(Please check all that apply and then circle the number of the statement which indicates your most important reason for receiving your results now).
- (1) ☐ I just want to know whether I have the gene. I am happier knowing.
 - (2) ☐ In order to decide whether to get prophylactic surgery.
 - (3) ☐ To assist me in other medical decisions.
 - (4) ☐ To make decisions about family planning.
 - (5) ☐ To make decisions about financial planning and insurance.
 - (6) ☐ To make lifestyle and other non-medical decisions.
 - (7) ☐ To find out the risk that may be transmitted to my children.
 - (8) ☐ Family members want me to get testing.
 - (9) ☐ I want to help other family members by providing them with my results.
 - (10) ☐ Other (please describe) _____

6. If you do not intend to obtain your results now, but may do so later, please indicate your reasons. B114.

(Please check all that apply and then circle the number of the statement which indicates your most important reason for delaying receiving your results).

- (1) ☐ I am happier not knowing.
- (2) ☐ There are no decisions I need to make at this time for which knowledge of my results would be useful.
- (3) ☐ It would be too upsetting to learn that I have a mutation associated with increased risk of cancer.
- (4) ☐ Knowing that I have a mutation would interfere with my life as it is now.
- (5) ☐ There would not be much I could now do to reduce my risk of cancer if I found out I had a mutation.
- (6) ☐ I am too worried about the effects of knowing my results on women in my family.
- (7) ☐ Family members do not want me to get testing.
- (8) ☐ Family members want me to get testing, but I am not ready to do so.
- (9) ☐ I want to wait until there is less risk to insurance coverage.
- (10) ☐ I want to wait until there is less risk to employment.
- (11) ☐ I am either too young or too old to benefit from knowing if I have a mutation.
- (12) ☐ I want to wait until more is known about breast/ovarian cancer genes and what can be done to reduce a women's risk of cancer.
- (13) ☐ I simply am not ready to make up my mind at this time.
- (14) ☐ Other (please describe) _____

7. If you do not intend to obtain your results now or in the future, please indicate your reasons. B115.

(Please check all that apply and then circle the number of the statement which indicates your most important reason for not receiving your results).

- (1) ☐ I am happier not knowing.
- (2) ☐ There are no decisions I need to make for which knowledge of my results would be useful.
- (3) ☐ It would be too upsetting to learn that I have a mutation associated with increased risk of cancer.
- (4) ☐ Knowing that I have a mutation would interfere with my life.
- (5) ☐ There would not be much I could do to reduce my risk of cancer if I found out I had a mutation.
- (6) ☐ I am too worried about the effects of knowing my results on women in my family.
- (7) ☐ Family members do not want me to get testing.
- (8) ☐ Risk to my insurance coverage.
- (9) ☐ Risk to my employment.
- (10) ☐ I am either too young or too old to benefit from knowing if I have a mutation.
- (11) ☐ I do not believe in obtaining personal genetic information.
- (12) ☐ Other (please describe) _____

PERSONAL ATTITUDES SECTION

1. For each of these statements, please indicate the extent to which you agree or disagree by circling the appropriate number. There are no right or wrong answers. We are only interested in your opinions.

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>		
a.	If you don't have your health, you don't have anything.	1	2	3	4	5	L5a.
b.	There are many things I care about more than my health.	1	2	3	4	5	L5b.
c.	Good health is of only minor importance in a happy life.	1	2	3	4	5	L5c.
d.	There is nothing more important than good health.	1	2	3	4	5	L5d.
e.	In uncertain times, I usually expect the best.	1	2	3	4	5	E1.
f.	It's easy for me to relax.	1	2	3	4	5	E2.
g.	If something can go wrong for me, it will.	1	2	3	4	5	E3.
h.	I always look on the bright side of things.	1	2	3	4	5	E4.
i.	I'm always optimistic about my future.	1	2	3	4	5	E5.
j.	I enjoy my friends a lot.	1	2	3	4	5	E6.
k.	It's important for me to keep busy.	1	2	3	4	5	E7.
l.	I hardly ever expect things to go my way.	1	2	3	4	5	E8.
m.	Things never work out the way I want them to.	1	2	3	4	5	E9.
n.	I don't get upset too easily.	1	2	3	4	5	E10.
o.	I'm a believer in the idea that "every cloud has a silver lining."	1	2	3	4	5	E11.
p.	I rarely count on good things happening to me.	1	2	3	4	5	E12.

GENETIC TESTING-SECTION 2

Using the following scales, please circle your response for each question.

		<i>Not At All</i> <i>Very Much</i>					<i>Not Appli- cable</i>	
1.	How distressing is it for you to know that you may be at increased risk for recurrence of breast or ovarian cancer because of your family history?	1	2	3	4	5	-8	B66.
2.	How distressing is it to be given the opportunity to be tested for an altered BRCA1/BRCA2, the altered genes associated with increased risk for breast and ovarian cancer?	1	2	3	4	5	-8	B67.
3.	How distressed do you expect to be if you get tested for an altered BRCA1/BRCA2 gene (just before you receive results)?	1	2	3	4	5	-8	B68.
4.	How distressed would you be if you took the test and found that you had an altered BRCA1/BRCA2 gene?	1	2	3	4	5	-8	B69.
5.	How distressed would you be if you took the test and found that you did not have an altered BRCA1/BRCA2 gene?	1	2	3	4	5	-8	B70.
6.	Overall, to what extent do you welcome the opportunity to be tested for an altered BRCA1/BRCA2 gene?	1	2	3	4	5	-8	B71.

		<i>Not At All</i> <i>All The Time</i>					
7.	How often do you worry about again developing breast or ovarian cancer?	1	2	3	4	5	B27.
8.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B28.
9.	How often do you worry about having an altered gene which conveys heightened risk for breast and ovarian cancer ?	1	2	3	4	5	B29.
10.	To what extent do these worries you have about having this altered gene interfere with your every day life?	1	2	3	4	5	B30.

11. When was the last time you had a mammogram? B32.

(Month/Year) _____ ☐(-8) Does not apply because of surgery.

12. How many times have you conducted a breast self-examination in the past six months? B33.
 _____ times ☐ (-8) Does not apply because of surgery.

13. How confident are you that you will perform breast self examination (BSE) ---
 13a. --as **frequently** as needed? (-8) ☐ Does Not Apply Because of Surgery. B34a.

Not at All Very Much So
 1 2 3 4 5 6 7

13b. --as **carefully and competently** as needed? B34b.
 (-8) ☐ Does Not Apply Because of Surgery

Not at All Very Much So
 1 2 3 4 5 6 7

For each of the following areas of your life, we ask you to make **two** ratings. First, indicate how much these decisions have been affected by being at increased risk for breast or ovarian cancer (based on your family history). Second, how much these decisions would be affected by the results of genetic testing ?

1	2	3	4	5
Not at all affected				Very much affected

		<u>Have been affected by being at increased risk for breast or ovarian cancer</u>					<u>Would be affected by the results of genetic testing</u>					
		1	2	3	4	5	1	2	3	4	5	
14.	Decisions about having children											B35a B35b
15.	Decisions about form of birth control											B36a B36b
16.	Decisions about which steps to take to prevent the recurrence of breast or ovarian cancer											B37a B37b
17.	Decisions about work and career											B38a B38b
18.	Decisions about savings and financial planning											B39a B39b
19.	Decisions about plans for the future											B40a B40b

20. **Answer the following question only if you have daughters.**

☐ Does Not Apply (Skip to the next question, 21)

B41.

1	2	3	4	5
Not at all affected				Very much affected

		<i>Have been affected by being at high risk for breast or ovarian cancer</i>					<i>Would be affected by the results of genetic testing</i>					B42 a/b
		1	2	3	4	5	1	2	3	4	5	
a-b.	Plans for your daughter's future											

21. Do you feel you have enough information about breast or ovarian cancer to make any decisions that might be necessary?

Not At All		Very Much				
1	2	3	4	5	6	7

B43.

22. Do you feel you are adequately informed about the benefits and drawbacks of genetic testing for risk of breast and ovarian cancer?

Not At All		Very Much				
1	2	3	4	5	6	7

B44.

23. Do you feel you are adequately informed about what you could do to reduce your risk of recurrence of breast and ovarian cancer if you had an altered BRCA1/BRCA2 gene?

Not At All		Very Much				
1	2	3	4	5	6	7

B45.

24. Do you feel you are adequately informed about the benefits and drawbacks of each option available to women who have an altered BRCA1/BRCA2 gene?

Not At All		Very Much				
1	2	3	4	5	6	7

B46.

25. Do you feel you are adequately informed about what it would mean for your children if you had an altered BRCA1/BRCA2 gene?

Not At All				Very Much		
1	2	3	4	5	6	7

B47.

26. How confident are you that you will make the best decision in deciding whether to be tested for BRCA1/BRCA2?

Not At All				Very Much		
1	2	3	4	5	6	7

B48a.

27. How confident are you that you would cope effectively with a finding that you had an altered BRCA1/BRCA2 gene?

Not At All				Very Much		
1	2	3	4	5	6	7

B48b.

28. How confident are you that you would make the best decision concerning your options if you were found to have an altered BRCA1/BRCA2 gene?

Not At All				Very Much		
1	2	3	4	5	6	7

B48c.

29. How confident are you that you would be able to follow through and cope effectively over the long haul if you were found to have an altered BRCA1/BRCA2 gene?

Not At All				Very Much		
1	2	3	4	5	6	7

B48d.

RELATIONSHIPS SECTION

1. Is there anyone in your life with whom you can share your most private feelings without holding back? C21.
(1) ☐ Yes (5) ☐ No
2. If married, can you share your most private feelings with your spouse/partner without holding back? C21a.
(1) ☐ Yes (5) ☐ No
3. If married, is there anyone besides your spouse/partner with whom you can share your most private feelings without holding back? C21b.
(1) ☐ Yes (5) ☐ No
-

LIFE EVENTS SECTION

1. Have any of the following events happened to you in the past six months? D1(a-m)
(Please Check All That Apply)
- | | |
|--|---|
| a. <input type="checkbox"/> You retired, were fired, or laid off from work. | g. <input type="checkbox"/> A close family member was seriously ill or injured. |
| b. <input type="checkbox"/> You were unemployed and looking for work. | h. <input type="checkbox"/> You had a marital separation or divorce. |
| c. <input type="checkbox"/> Your spouse retired, was fired, or laid off from work. | i. <input type="checkbox"/> You had serious troubles with relatives or close friends. |
| d. <input type="checkbox"/> Your spouse was unemployed and looking for work. | j. <input type="checkbox"/> Your spouse had troubles or difficulties with relatives or close friends. |
| e. <input type="checkbox"/> You had problems with the police or court. | k. <input type="checkbox"/> A close family member died. |
| f. <input type="checkbox"/> You got into serious financial difficulties. | l. <input type="checkbox"/> A close friend or relative died. |
| | m. <input type="checkbox"/> You were seriously ill or injured. |
-

MARRIAGE SECTION

The following questions apply to persons who are married or living with a partner. *If you are not married or living with a partner, please check the box and skip to page 11, Mood Section.*

Not married or living with a partner ☐

Ea.

Most people have disagreements in their relationships. Please indicate by circling the number that represents the extent of agreement or disagreement experienced between you and your spouse/partner **DURING THE PAST MONTH**.

		<i>Always Disagree</i>	<i>Almost Always Disagree</i>	<i>Fre- quently Disagree</i>	<i>Occa- sionally Disagree</i>	<i>Almost Always Agree</i>	<i>Always Agree</i>	
1.	Religious matters	1	2	3	4	5	6	H3.
2.	Demonstration of affection	1	2	3	4	5	6	H4.
3.	Sex relations	1	2	3	4	5	6	H6.
4.	Conventionality (correct or proper behavior)	1	2	3	4	5	6	H7.
5.	Making major decisions	1	2	3	4	5	6	H12.
6.	Career decisions	1	2	3	4	5	6	H15.

		<i>Never</i>	<i>Rarely</i>	<i>Occa- sionally</i>	<i>More often than most</i>	<i>Most of the time</i>	<i>All of the time</i>	
7.	How often do you discuss or have you considered divorce, separation, or terminating your relationship?	1	2	3	4	5	6	H16.
8.	Do you ever regret that you married (or lived together)?	1	2	3	4	5	6	H20.
9.	How often do you and your partner quarrel?	1	2	3	4	5	6	H21.
10.	How often do you and your spouse/partner "get on each other's nerves?"	1	2	3	4	5	6	H22.

		<i>None of Them</i>	<i>Very Few of Them</i>	<i>Some of Them</i>	<i>Most of Them</i>	<i>All of Them</i>
11.	To what extent do you and your spouse/partner share interests together?	1	2	3	4	5

H24.

How often would you say the following events occur between you and your spouse/partner?

		<i>Never</i>	<i>Less than once a month</i>	<i>About twice a month</i>	<i>About twice a week</i>	<i>Once a day</i>	<i>More Often</i>
12.	Have a stimulating exchange of ideas	1	2	3	4	5	6
13.	Calmly discuss something	1	2	3	4	5	6
14.	Work together on a project	1	2	3	4	5	6

H25.

H27.

H28.

15. Considering **only the positive feelings** you have towards your spouse/partner, and **ignoring the negative ones**, please rate how positive these feelings are:

H33.

Not At All Positive					Extremely Positive				
1	2	3	4	5	6	7	8	9	10

16. Considering **only the negative feelings** you have towards your spouse/partner, and **ignoring the positive ones**, please rate how negative these feelings are:

H34.

Not At All Negative					Extremely Negative				
1	2	3	4	5	6	7	8	9	10

17. The following questions concern your spouse/partner's involvement in your health care.

		<i>Never</i> <i>Very Often</i>				
a.	How often does your spouse/partner go with you to your appointments with doctors?	1	2	3	4	5
b.	How often does your spouse/partner talk with your doctor or other medical personnel about your risk of breast or ovarian cancer?	1	2	3	4	5
c.	How often does your spouse/partner keep track of what you need to do about your risk for breast or ovarian cancer?	1	2	3	4	5
d.	How often does your spouse/partner change their activities to assist you in your health care?	1	2	3	4	5

H35a.

H35b.

H35c.

H35d.

18. Has your spouse/partner attended individual, family or group sessions to become informed about your risk for breast or ovarian cancer and what can be done? H36.
 (1) ☐ Yes (5) ☐ No

19. How much contact has your spouse/partner had with medical personnel concerning your risk for breast or ovarian cancer? H37.

Very Little or None							A lot
1	2	3	4	5	6	7	

20. Do you feel your spouse/partner is adequately informed concerning your risk for breast or ovarian cancer and what can be done about it? H38.

Not at All						Very Much
1	2	3	4	5	6	7

21. To what extent are you satisfied with your spouse/partner's involvement in your health care? H39.

Not at All						Very Much
1	2	3	4	5	6	7

MOOD SECTION

1. In the **past year**, have you had two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun? I12.
 (1) ☐ Yes (5) ☐ No (Skip to Question 2)

1a. During this period, did your work or relationships suffer? I12a.
 (1) ☐ Yes (5) ☐ No

1b. During this period, did you get counseling or psychotherapy? I12b.
 (1) ☐ Yes (5) ☐ No

1c. During this period, did you get medication for this condition? I12c.
 (1) ☐ Yes (5) ☐ No

2. Are you **currently** receiving counseling, psychotherapy, or medication for depression or emotional problems? I13.
 (1) ☐ Yes (5) ☐ No

SYMPTOMS OF STRAIN SECTION

LISTED BELOW ARE SOME SYMPTOMS OF STRAIN THAT PEOPLE SOMETIMES HAVE. *Please Read Each One Carefully And Check The Answer Which Best Reflects How Much That Symptom Has Bothered You During the **Past Three Months**.*

		<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Extremely</u>	
1.	Suddenly scared for no reason	1	2	3	4	K1.
2.	Feeling fearful	1	2	3	4	K2.
3.	Faintness, dizziness, or weakness	1	2	3	4	K3.
4.	Nervousness or shakiness inside	1	2	3	4	K4.
5.	Heart pounding or racing	1	2	3	4	K5.
6.	Trembling	1	2	3	4	K6.
7.	Feeling tense or keyed up	1	2	3	4	K7.
8.	Headaches	1	2	3	4	K8.
9.	Spells of terror or panic	1	2	3	4	K9.
10.	Feeling restless, can't sit still	1	2	3	4	K10.
11.	Feeling low in energy--slowed down	1	2	3	4	K11.
12.	Blaming yourself for things	1	2	3	4	K12.
13.	Crying easily	1	2	3	4	K13.
14.	Loss of sexual interest or pleasure	1	2	3	4	K14.
15.	Poor appetite	1	2	3	4	K15.
16.	Difficulty falling asleep, staying asleep	1	2	3	4	K16.
17.	Feeling hopeless about the future	1	2	3	4	K17.
18.	Feeling blue	1	2	3	4	K18.
19.	Feeling lonely	1	2	3	4	K19.
20.	Feeling trapped or caught	1	2	3	4	K20.
21.	Worrying too much about things	1	2	3	4	K21.
22.	Feeling no interest in things	1	2	3	4	K22.
23.	Thoughts of ending your life	1	2	3	4	K23.
24.	Feeling everything is an effort	1	2	3	4	K24.

25.	Feelings of worthlessness	1	2	3	4
-----	---------------------------	---	---	---	---

K25.

COPING SECTION

1. Sometimes people can find unexpected benefits in difficulties. We are interested in the ways in which you might have made positive use of your risk for breast or ovarian cancer. For each of the statements below, indicate the degree to which your life is affected positively by your risk of breast or ovarian cancer.

		<i>Not At All</i>	<i>A Very Small Degree</i>	<i>A Small Degree</i>	<i>A Moderate Degree</i>	<i>A Great Degree</i>	<i>A Very Great Degree</i>	
a.	My priorities about what is important in life.	1	2	3	4	5	6	L6a.
b.	I'm more likely to try to change things which need changing.	1	2	3	4	5	6	L6b.
c.	An appreciation for the value of my own life.	1	2	3	4	5	6	L6c.
d.	A feeling of self-reliance.	1	2	3	4	5	6	L6d.
e.	A better understanding of spiritual matters.	1	2	3	4	5	6	L6e.
f.	Knowing that I can count on people in times of troubles.	1	2	3	4	5	6	L6f.
g.	A sense of closeness with others.	1	2	3	4	5	6	L6g.
h.	Knowing I can handle difficulties.	1	2	3	4	5	6	L6h.
i.	A willingness to express my emotions.	1	2	3	4	5	6	L6i.
j.	Being able to accept the way things work out.	1	2	3	4	5	6	L6j.
k.	Appreciating each day.	1	2	3	4	5	6	L6k.
l.	Having compassion for others.	1	2	3	4	5	6	L6l.
m.	I'm able to do better things with my life.	1	2	3	4	5	6	L6m.
n.	New opportunities are available which wouldn't have been otherwise.	1	2	3	4	5	6	L6n.

2. This set of questions deals with ways you've been coping with the stress in your life that comes with being at risk for breast or ovarian cancer. There are many ways people try to deal with problems. Obviously, different people deal with things in different ways, but we are interested in how you've tried to deal with it. Each item says something about a particular way of coping. We want to know *to what extent* you've been doing what the item says, how *much* or how *frequently*. Don't answer on the basis of whether it seems to be working but just whether or not you're doing it. Use these response choices below and try not to let one answer influence another. Please make your answers as true FOR YOU as you can.

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>	
a.	I've been turning to work or other activities to take my mind off things.	1	2	3	4	L7a.
b.	I've been concentrating my efforts on doing something about my situation.	1	2	3	4	L7b.
c.	I've been saying to myself "this isn't possible."	1	2	3	4	L7c.
d.	I've been using alcohol or other drugs to make myself feel better.	1	2	3	4	L7d.
e.	I've been getting emotional support from others.	1	2	3	4	L7e.
f.	I've been giving up trying to deal with it.	1	2	3	4	L7f.
g.	I've been taking action to try to make the situation better.	1	2	3	4	L7g.
h.	I've been refusing to believe that it is possible that I have an altered gene.	1	2	3	4	L7h.
i.	I've been saying things to let my unpleasant feelings escape.	1	2	3	4	L7i.
j.	I've been using alcohol or other drugs to help me get through it.	1	2	3	4	L7j.
k.	I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4	L7k.
l.	I've been trying to come up with a strategy about what to do.	1	2	3	4	L7l.
m.	I've been getting comfort and understanding from someone.	1	2	3	4	L7m.

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>	
n.	I've been giving up the attempt to cope.	1	2	3	4	L7n.
o.	I've been accepting the possibility that I might have an altered gene.	1	2	3	4	L7o.
p.	I've been expressing my negative feelings.	1	2	3	4	L7p.
q.	I've been trying to find comfort in my religion or spiritual beliefs.	1	2	3	4	L7q.
r.	I've been learning to live with the possibility that I might have the gene.	1	2	3	4	L7r.
s.	I've been thinking hard about what steps to take.	1	2	3	4	L7s.
t.	I've been praying or meditating.	1	2	3	4	L7t.
u.	I've been making fun of the situation.	1	2	3	4	L7u.

3. The following items are to be answered only by those women who are married or living with a partner.

☐ Not married or living with a partner

L8.

(Skip to the last section on next page)

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>	
a.	I've been denying or hiding my anger around my spouse/partner.	1	2	3	4	L8a.
b.	I've been denying or hiding my worries around my spouse/partner.	1	2	3	4	L8b.
c.	I've been avoiding talking about my problems around my spouse/partner.	1	2	3	4	L8c.
d.	I've acted more positive around my spouse/partner than I feel.	1	2	3	4	L8d.

BACKGROUND DATA SECTION

These are a few questions about your religious background that we forgot to ask on the original questionnaire.

1. Religion: Catholic (1) ☐ Protestant (4) ☐ **A3.**
Jewish (2) ☐ Buddhist (5) ☐
Muslim (3) ☐ Other (6) ☐
None (7) ☐

- 1a. How often do you attend religious services? **A3a.**
(1) (5)
☐ Less Often Than Once a Month ☐ A Few Times A Month or More

- 1b. How important are religious and spiritual beliefs in your life? **A3b.**
Not at All 1 2 3 4 Very Important 5

Once again, We thank you for all of your valued participation in this study.

TODAY'S DATE _____

ID _____

PRE-RESULTS ASSESSMENT - U

You may notice that some of these questions were asked in previous questionnaires, but many of the questions are new. We are asking them again because we are interested in feelings and attitudes which may change over time.
THANK YOU VERY MUCH!

GENETIC TESTING-SECTION 1

1. Have you met with anyone to have genetic counseling? **B24.**
(1) ☐ Yes (5) ☐ No
2. Has any member of your family met with someone to have genetic counseling? **B25.**
(1) ☐ Yes (5) ☐ No
3. As the opportunity to get testing has approached, has your interest in getting results changed? **B74.**
- | | | | | |
|-------------------------------------|------------------------------------|---------------------------|------------------------------------|-------------------------------------|
| Decreased
Very Much
1 | Decreased
Slightly
2 | No
Change
3 | Increased
Slightly
4 | Increased
Very Much
5 |
|-------------------------------------|------------------------------------|---------------------------|------------------------------------|-------------------------------------|
4. At this time, what is your decision regarding receiving your genetic results? **B112.**
(1) ☐ I will probably or definitely receive my results now, as soon as they are offered.
(Skip to Question 5)
(3) ☐ I do not intend to receive my results now, but may do so later. (Skip to Question 6)
(5) ☐ I do not intend to receive my results now or in the future. (Skip to Question 7)
5. If you will probably or definitely obtain your results now, as soon as they are being offered to you, what are your reasons for doing so? **B113.**
(Please check all that apply and then circle the number of the statement which indicates your most important reason for receiving your results now).
- (1) ☐ I just want to know whether I have the gene. I am happier knowing.
(2) ☐ In order to decide whether to get prophylactic surgery.
(3) ☐ To assist me in other medical decisions.
(4) ☐ To make decisions about family planning.
(5) ☐ To make decisions about financial planning and insurance.
(6) ☐ To make lifestyle and other non-medical decisions.
(7) ☐ To find out the risk that may be transmitted to my children.
(8) ☐ Family members want me to get testing.
(9) ☐ I want to help other family members by providing them with my results.
(10) ☐ Other (please describe) _____

6. If you do not intend to obtain your results now, but may do so later, please indicate your reasons. B114.

(Please check all that apply and then circle the number of the statement which indicates your most important reason for delaying receiving your results).

- (1) ☐ I am happier not knowing.
- (2) ☐ There are no decisions I need to make at this time for which knowledge of my results would be useful.
- (3) ☐ It would be too upsetting to learn that I have a mutation associated with increased risk of cancer.
- (4) ☐ Knowing that I have a mutation would interfere with my life as it is now.
- (5) ☐ There would not be much I could now do to reduce my risk of cancer if I found out I had a mutation.
- (6) ☐ I am too worried about the effects of knowing my results on women in my family.
- (7) ☐ Family members do not want me to get testing.
- (8) ☐ Family members want me to get testing, but I am not ready to do so.
- (9) ☐ I want to wait until there is less risk to insurance coverage.
- (10) ☐ I want to wait until there is less risk to employment.
- (11) ☐ I am either too young or too old to benefit from knowing if I have a mutation.
- (12) ☐ I want to wait until more is known about breast/ovarian cancer genes and what can be done to reduce a women's risk of cancer.
- (13) ☐ I simply am not ready to make up my mind at this time.
- (14) ☐ Other (please describe) _____

7. If you do not intend to obtain your results now or in the future, please indicate your reasons. B115.

(Please check all that apply and then circle the number of the statement which indicates your most important reason for not receiving your results).

- (1) ☐ I am happier not knowing.
- (2) ☐ There are no decisions I need to make for which knowledge of my results would be useful.
- (3) ☐ It would be too upsetting to learn that I have a mutation associated with increased risk of cancer.
- (4) ☐ Knowing that I have a mutation would interfere with my life.
- (5) ☐ There would not be much I could do to reduce my risk of cancer if I found out I had a mutation.
- (6) ☐ I am too worried about the effects of knowing my results on women in my family.
- (7) ☐ Family members do not want me to get testing.
- (8) ☐ Risk to my insurance coverage.
- (9) ☐ Risk to my employment.
- (10) ☐ I am either too young or too old to benefit from knowing if I have a mutation.
- (11) ☐ I do not believe in obtaining personal genetic information.
- (12) ☐ Other (please describe) _____

PERSONAL ATTITUDES SECTION

1. For each of these statements, please indicate the extent to which you agree or disagree by circling the appropriate number. There are no right or wrong answers. We are only interested in your opinions.

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>		
a.	If you don't have your health, you don't have anything.	1	2	3	4	5	L5a.
b.	There are many things I care about more than my health.	1	2	3	4	5	L5b.
c.	Good health is of only minor importance in a happy life.	1	2	3	4	5	L5c.
d.	There is nothing more important than good health.	1	2	3	4	5	L5d.
e.	In uncertain times, I usually expect the best.	1	2	3	4	5	E1.
f.	It's easy for me to relax.	1	2	3	4	5	E2.
g.	If something can go wrong for me, it will.	1	2	3	4	5	E3.
h.	I always look on the bright side of things.	1	2	3	4	5	E4.
i.	I'm always optimistic about my future.	1	2	3	4	5	E5.
j.	I enjoy my friends a lot.	1	2	3	4	5	E6.
k.	It's important for me to keep busy.	1	2	3	4	5	E7.
l.	I hardly ever expect things to go my way.	1	2	3	4	5	E8.
m.	Things never work out the way I want them to.	1	2	3	4	5	E9.
n.	I don't get upset too easily.	1	2	3	4	5	E10.
o.	I'm a believer in the idea that "every cloud has a silver lining."	1	2	3	4	5	E11.
p.	I rarely count on good things happening to me.	1	2	3	4	5	E12.

GENETIC TESTING-SECTION 2

Using the following scales, please circle your response for each question.

		<i>Not At All</i>					<i>Very Much</i>	<i>Not Appli- cable</i>	
		1	2	3	4	5	-8		
1.	How distressing is it for you to know that you may be at increased risk for breast or ovarian cancer because of your family history?							B66.	
2.	How distressing is it to be given the opportunity to be tested for an altered BRCA-1/BRCA2, the altered genes associated with increased risk for breast and ovarian cancer?							B67.	
3.	How distressed do you expect to be if you get tested for an altered BRCA-1/BRCA2 gene (just before you receive results)?							B68.	
4.	How distressed would you be if you took the test and found that you had an altered BRCA-1/BRCA2 gene?							B69.	
5.	How distressed would you be if you took the test and found that you did not have an altered BRCA1/BRCA2 gene?							B70.	
6.	Overall, to what extent do you welcome the opportunity to be tested for an altered BRCA-1/BRCA2 gene?							B71.	

		<i>Not At All</i>			<i>All The Time</i>		
		1	2	3	4	5	
7.	How often do you worry about developing breast or ovarian cancer?						B27.
8.	To what extent do these worries interfere with your every day life?						B28.
9.	How often do you worry about having an altered gene which conveys heightened risk for breast and ovarian cancer?						B29.
10.	To what extent do these worries you have about having this altered gene interfere with your every day life?						B30.

11. When was the last time you had a mammogram? B32.

(Month/Year) _____ ☐ (-8) Does not apply because of surgery.

12. How many times have you conducted a breast self-examination in the past six months? B33.
 _____ times ☐ (-8) Does not apply because of surgery.

13. How confident are you that you will perform breast self examination (BSE) ---
 13a. --as **frequently** as needed? (-8) ☐ Does Not Apply Because of Surgery. B34a.

Not at All Very Much So
 1 2 3 4 5 6 7

13b. --as **carefully and competently** as needed? B34b.
 (-8) ☐ Does Not Apply Because of Surgery

Not at All Very Much So
 1 2 3 4 5 6 7

For each of the following areas of your life, we ask you to make **two** ratings. First, indicate how much these decisions have been affected by **being at risk for breast or ovarian cancer** (based on your family history). Second, how much these decisions would be affected by **the results of genetic testing**?

1	2	3	4	5
Not at all affected				Very much affected

		<u>Have been affected by being at risk for breast or ovarian cancer</u>					<u>Would be affected by the results of genetic testing</u>					
		1	2	3	4	5	1	2	3	4	5	
14.	Decisions about having children											B35a B35b
15.	Decisions about form of birth control											B36a B36b
16.	Decisions about which steps to take to prevent the occurrence of breast or ovarian cancer											B37a B37b
17.	Decisions about work and career											B38a B38b
18.	Decisions about savings and financial planning											B39a B39b
19.	Decisions about plans for the future											B40a B40b

20. **Answer the following question only if you have daughters.**

☐ Does Not Apply (Skip to the next question, 22)

B41.

1	2	3	4	5
Not at all affected				Very much affected

		<u>Have been affected by being at high risk for breast or ovarian cancer</u>					<u>Would be affected by the results of genetic testing</u>					B42 a/b
		1	2	3	4	5	1	2	3	4	5	
a-b.	Plans for your daughter's future											

21. Do you feel you have enough information about breast or ovarian cancer to make any decisions that might be necessary?

Not At All		Very Much				
1	2	3	4	5	6	7

B43.

22. Do you feel you are adequately informed about the benefits and drawbacks of genetic testing for risk of breast and ovarian cancer?

Not At All		Very Much				
1	2	3	4	5	6	7

B44.

23. Do you feel you are adequately informed about what you could do to reduce your risk of breast and ovarian cancer if you had an altered BRCA1/BRCA2 gene?

Not At All		Very Much				
1	2	3	4	5	6	7

B45.

24. Do you feel you are adequately informed about the benefits and drawbacks of each option available to women who have an altered BRCA1/BRCA2 gene?

Not At All		Very Much				
1	2	3	4	5	6	7

B46.

25. Do you feel you are adequately informed about what it would mean for your children if you had an altered BRCA1/BRCA2 gene?

Not At All		Very Much				
1	2	3	4	5	6	7

B47.

26. How confident are you that you will make the best decision in deciding whether to be tested for BRCA1/BRCA2?

Not At All		Very Much				
1	2	3	4	5	6	7

B48a.

27. How confident are you that you would cope effectively with a finding that you had an altered BRCA1/BRCA2 gene?

Not At All		Very Much				
1	2	3	4	5	6	7

B48b.

28. How confident are you that you would make the best decision concerning your options if you were found to have an altered BRCA1/BRCA2 gene?

Not At All		Very Much				
1	2	3	4	5	6	7

B48c.

29. How confident are you that you would be able to follow through and cope effectively over the long haul if you were found to have an altered BRCA1/BRCA2 gene?

Not At All		Very Much				
1	2	3	4	5	6	7

B48d.

RELATIONSHIPS SECTION

1. Is there anyone in your life with whom you can share your most private feelings without holding back? C21.
(1) ☐ Yes (5) ☐ No
2. If married, can you share your most private feelings with your spouse/partner without holding back? C21a.
(1) ☐ Yes (5) ☐ No
3. If married, is there anyone besides your spouse/partner with whom you can share your most private feelings without holding back? C21b.
(1) ☐ Yes (5) ☐ No
-

LIFE EVENTS SECTION

1. Have any of the following events happened to you in the past six months? D1(a-m)
(Please Check All That Apply)
- | | |
|--|---|
| a. <input type="checkbox"/> You retired, were fired, or laid off from work. | g. <input type="checkbox"/> A close family member was seriously ill or injured. |
| b. <input type="checkbox"/> You were unemployed and looking for work. | h. <input type="checkbox"/> You had a marital separation or divorce. |
| c. <input type="checkbox"/> Your spouse retired, was fired, or laid off from work. | i. <input type="checkbox"/> You had serious troubles with relatives or close friends. |
| d. <input type="checkbox"/> Your spouse was unemployed and looking for work. | j. <input type="checkbox"/> Your spouse had troubles or difficulties with relatives or close friends. |
| e. <input type="checkbox"/> You had problems with the police or court. | k. <input type="checkbox"/> A close family member died. |
| f. <input type="checkbox"/> You got into serious financial difficulties. | l. <input type="checkbox"/> A close friend or relative died. |
| | m. <input type="checkbox"/> You were seriously ill or injured. |
-

MARRIAGE SECTION

The following questions apply to persons who are married or living with a partner. *If you are not married or living with a partner, please check the box and skip to page 11, Mood Section.*

Not married or living with a partner ☐

Ea.

Most people have disagreements in their relationships. Please indicate by circling the number that represents the extent of agreement or disagreement experienced between you and your spouse/partner **DURING THE PAST MONTH**.

		<i>Always Disagree</i>	<i>Almost Always Disagree</i>	<i>Frequently Disagree</i>	<i>Occasionally Disagree</i>	<i>Almost Always Agree</i>	<i>Always Agree</i>	
1.	Religious matters	1	2	3	4	5	6	H3.
2.	Demonstration of affection	1	2	3	4	5	6	H4.
3.	Sex relations	1	2	3	4	5	6	H6.
4.	Conventionality (correct or proper behavior)	1	2	3	4	5	6	H7.
5.	Making major decisions	1	2	3	4	5	6	H12.
6.	Career decisions	1	2	3	4	5	6	H15.

		<i>Never</i>	<i>Rarely</i>	<i>Occasionally</i>	<i>More often than most</i>	<i>Most of the time</i>	<i>All of the time</i>	
7.	How often do you discuss or have you considered divorce, separation, or terminating your relationship?	1	2	3	4	5	6	H16.
8.	Do you ever regret that you married (or lived together)?	1	2	3	4	5	6	H20.
9.	How often do you and your partner quarrel?	1	2	3	4	5	6	H21.
10.	How often do you and your spouse/partner "get on each other's nerves?"	1	2	3	4	5	6	H22.

		<i>None of Them</i>	<i>Very Few of Them</i>	<i>Some of Them</i>	<i>Most of Them</i>	<i>All of Them</i>
11.	To what extent do you and your spouse/partner share interests together?	1	2	3	4	5

H24.

How often would you say the following events occur between you and your spouse/partner?

		<i>Never</i>	<i>Less than once a month</i>	<i>About twice a month</i>	<i>About twice a week</i>	<i>Once a day</i>	<i>More Often</i>
12.	Have a stimulating exchange of ideas	1	2	3	4	5	6
13.	Calmly discuss something	1	2	3	4	5	6
14.	Work together on a project	1	2	3	4	5	6

H25.

H27.

H28.

15. Considering **only the positive feelings** you have towards your spouse/partner, and **ignoring the negative ones**, please rate how positive these feelings are:

H33.

Not At All Positive					Extremely Positive				
1	2	3	4	5	6	7	8	9	10

16. Considering **only the negative feelings** you have towards your spouse/partner, and **ignoring the positive ones**, please rate how negative these feelings are:

H34.

Not At All Negative					Extremely Negative				
1	2	3	4	5	6	7	8	9	10

17. The following questions concern your spouse/partner's involvement in your health care.

		<i>Never</i> <i>Very Often</i>				
a.	How often does your spouse/partner go with you to your appointments with doctors?	1	2	3	4	5
b.	How often does your spouse/partner talk with your doctor or other medical personnel about your risk for breast or ovarian cancer?	1	2	3	4	5
c.	How often does your spouse/partner keep track of what you need to do about your risk for breast or ovarian cancer?	1	2	3	4	5
d.	How often does your spouse/partner change their activities to assist you in your health care?	1	2	3	4	5

H35a.

H35b.

H35c.

H35d.

18. Has your spouse/partner attended individual, family or group sessions to become informed about your risk for breast or ovarian cancer and what can be done? H36.
(1) ☐ Yes (5) ☐ No

19. How much contact has your spouse/partner had with medical personnel concerning your risk for breast or ovarian cancer? H37.

Very Little
or None
1 2 3 4 5 6 A lot
7

20. Do you feel your spouse/partner is adequately informed concerning your risk for breast or ovarian cancer and what can be done about it? H38.

Not at All
1 2 3 4 5 6 Very Much
7

21. To what extent are you satisfied with your spouse/partner's involvement in your health care? H39.

Not at All
1 2 3 4 5 6 Very Much
7

MOOD SECTION

1. In the past year, have you had two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun? I12.
(1) ☐ Yes (5) ☐ No (Skip to Question 2)

1a. During this period, did your work or relationships suffer? I12a.
(1) ☐ Yes (5) ☐ No

1b. During this period, did you get counseling or psychotherapy? I12b.
(1) ☐ Yes (5) ☐ No

1c. During this period, did you get medication for this condition? I12c.
(1) ☐ Yes (5) ☐ No

2. Are you currently receiving counseling, psychotherapy, or medication for depression or emotional problems? I13.
(1) ☐ Yes (5) ☐ No

SYMPTOMS OF STRAIN SECTION

LISTED BELOW ARE SOME SYMPTOMS OF STRAIN THAT PEOPLE SOMETIMES HAVE. *Please Read Each One Carefully And Check The Answer Which Best Reflects How Much That Symptom Has Bothered You During the Past Three Months.*

		<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Extremely</u>	
1.	Suddenly scared for no reason	1	2	3	4	K1.
2.	Feeling fearful	1	2	3	4	K2.
3.	Faintness, dizziness, or weakness	1	2	3	4	K3.
4.	Nervousness or shakiness inside	1	2	3	4	K4.
5.	Heart pounding or racing	1	2	3	4	K5.
6.	Trembling	1	2	3	4	K6.
7.	Feeling tense or keyed up	1	2	3	4	K7.
8.	Headaches	1	2	3	4	K8.
9.	Spells of terror or panic	1	2	3	4	K9.
10.	Feeling restless, can't sit still	1	2	3	4	K10.
11.	Feeling low in energy--slowed down	1	2	3	4	K11.
12.	Blaming yourself for things	1	2	3	4	K12.
13.	Crying easily	1	2	3	4	K13.
14.	Loss of sexual interest or pleasure	1	2	3	4	K14.
15.	Poor appetite	1	2	3	4	K15.
16.	Difficulty falling asleep, staying asleep	1	2	3	4	K16.
17.	Feeling hopeless about the future	1	2	3	4	K17.
18.	Feeling blue	1	2	3	4	K18.
19.	Feeling lonely	1	2	3	4	K19.
20.	Feeling trapped or caught	1	2	3	4	K20.
21.	Worrying too much about things	1	2	3	4	K21.
22.	Feeling no interest in things	1	2	3	4	K22.
23.	Thoughts of ending your life	1	2	3	4	K23.
24.	Feeling everything is an effort	1	2	3	4	K24.

25.	Feelings of worthlessness	1	2	3	4
-----	---------------------------	---	---	---	---

K25.

COPING SECTION

1. Sometimes people can find unexpected benefits in difficulties. We are interested in the ways in which you might have made positive use of your risk for breast or ovarian cancer. For each of the statements below, indicate the degree to which your life is affected positively by your risk of breast or ovarian cancer.

		<i>Not At All</i>	<i>A Very Small Degree</i>	<i>A Small Degree</i>	<i>A Moderate Degree</i>	<i>A Great Degree</i>	<i>A Very Great Degree</i>	
a.	My priorities about what is important in life.	1	2	3	4	5	6	L6a.
b.	I'm more likely to try to change things which need changing.	1	2	3	4	5	6	L6b.
c.	An appreciation for the value of my own life.	1	2	3	4	5	6	L6c.
d.	A feeling of self-reliance.	1	2	3	4	5	6	L6d.
e.	A better understanding of spiritual matters.	1	2	3	4	5	6	L6e.
f.	Knowing that I can count on people in times of troubles.	1	2	3	4	5	6	L6f.
g.	A sense of closeness with others.	1	2	3	4	5	6	L6g.
h.	Knowing I can handle difficulties.	1	2	3	4	5	6	L6h.
i.	A willingness to express my emotions.	1	2	3	4	5	6	L6i.
j.	Being able to accept the way things work out.	1	2	3	4	5	6	L6j.
k.	Appreciating each day.	1	2	3	4	5	6	L6k.
l.	Having compassion for others.	1	2	3	4	5	6	L6l.
m.	I'm able to do better things with my life.	1	2	3	4	5	6	L6m.
n.	New opportunities are available which wouldn't have been otherwise.	1	2	3	4	5	6	L6n.

2. This set of questions deals with ways you've been coping with the stress in your life that comes with being at risk for breast or ovarian cancer. There are many ways people try to deal with problems. Obviously, different people deal with things in different ways, but we are interested in how you've tried to deal with it. Each item says something about a particular way of coping. We want to know *to what extent* you've been doing what the item says, how *much* or how *frequently*. Don't answer on the basis of whether it seems to be working but just whether or not you're doing it. Use these response choices below and try not to let one answer influence another. Please make your answers as true FOR YOU as you can..

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>	
a.	I've been turning to work or other activities to take my mind off things.	1	2	3	4	L7a.
b.	I've been concentrating my efforts on doing something about my situation.	1	2	3	4	L7b.
c.	I've been saying to myself "this isn't possible."	1	2	3	4	L7c.
d.	I've been using alcohol or other drugs to make myself feel better.	1	2	3	4	L7d.
e.	I've been getting emotional support from others.	1	2	3	4	L7e.
f.	I've been giving up trying to deal with it.	1	2	3	4	L7f.
g.	I've been taking action to try to make the situation better.	1	2	3	4	L7g.
h.	I've been refusing to believe that it is possible that I have an altered gene.	1	2	3	4	L7h.
i.	I've been saying things to let my unpleasant feelings escape.	1	2	3	4	L7i.
j.	I've been using alcohol or other drugs to help me get through it.	1	2	3	4	L7j.
k.	I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4	L7k.
l.	I've been trying to come up with a strategy about what to do.	1	2	3	4	L7l.
m.	I've been getting comfort and understanding from someone.	1	2	3	4	L7m.

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>
n.	I've been giving up the attempt to cope.	1	2	3	4
o.	I've been accepting the possibility that I might have an altered gene.	1	2	3	4
p.	I've been expressing my negative feelings.	1	2	3	4
q.	I've been trying to find comfort in my religion or spiritual beliefs.	1	2	3	4
r.	I've been learning to live with the possibility that I might have the gene.	1	2	3	4
s.	I've been thinking hard about what steps to take.	1	2	3	4
t.	I've been praying or meditating.	1	2	3	4
u.	I've been making fun of the situation.	1	2	3	4

L7n.

L7o.

L7p.

L7q.

L7r.

L7s.

L7t.

L7u.

3. The following items are to be answered only by those women who are married or living with a partner.

☐ Not married or living with a partner

L8.

(Skip to the last section on next page)

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>
a.	I've been denying or hiding my anger around my spouse/partner.	1	2	3	4
b.	I've been denying or hiding my worries around my spouse/partner.	1	2	3	4
c.	I've been avoiding talking about my problems around my spouse/partner.	1	2	3	4
d.	I've acted more positive around my spouse/partner than I feel.	1	2	3	4

L8a.

L8b.

L8c.

L8d.

BACKGROUND DATA SECTION

These are a few questions about your religious background that we forgot to ask on the original questionnaire.

1. Religion: Catholic (1) ☐ Protestant (4) ☐ **A 3.**
Jewish (2) ☐ Buddhist (5) ☐
Muslim (3) ☐ Other (6) ☐
None (7) ☐
- 1a. How often do you attend religious services? **A 3a.**
(1) (5)
☐ Less Often Than Once a Month ☐ A Few Times A Month or More
- 1b. How important are religious and spiritual beliefs in your life? **A 3b.**
Not at All 1 2 3 4 Very Important 5

Once again, We thank you for all of your valued participation in this study.

POST-RESULTS 1: *One to Two Months***Genetic Testing Section**

1. When did you receive your results of genetic testing? _____ B101
2. Are you the only person in your family who has gotten genetic testing for breast and ovarian cancer?
(1) ☐ Yes (5) ☐ No B101a
3. What were the results of testing? B101b
- 1 ☐ Negative (uninformative) for BRCA1/BRCA2 and all Family members who were tested were negative for BRCA1/BRCA2 OR you are the only person in your family who has gotten testing (Skip to Question 4)
- 2 ☐ Negative (informative) for BRCA1/BRCA2, but at least one family member was found to be Positive (Skip to Question 4)
- 3 ☐ Positive for BRCA1/BRCA2 (Skip to Next page, Question 5)
4. When you took the test and found out that you did not have an altered gene associated with high risk for breast and ovarian cancer, what were your reactions?

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>			<i>N/A</i>	
a.	I felt wonderful.	1	2	3	4	5	-8		B18a_a.
b.	I felt I had been told what I knew all along.	1	2	3	4	5	-8		B18a_b.
c.	I felt relieved.	1	2	3	4	5	-8		B18a_c.
d.	I did not believe the results.	1	2	3	4	5	-8		B18a_d.
e.	I fell apart emotionally.	1	2	3	4	5	-8		B18a_e.
f.	I felt guilty.	1	2	3	4	5	-8		B18a_f.
g.	I still felt anxious.	1	2	3	4	5	-8		B18a_g.
h.	I felt angry.	1	2	3	4	5	-8		B18a_h.
i.	I felt prepared for the future.	1	2	3	4	5	-8		B18a_i.
j.	I felt I had done all I needed to do.	1	2	3	4	5	-8		B18a_j.
k.	I did not feel very differently.	1	2	3	4	5	-8		B18a_k.

INTERVIEWER: Skip to Page 3, Question 6

5. When you took the test and found out that you **had** an altered gene associated with high risk for breast and ovarian cancer, what were your reactions?

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>		<i>N/A</i>	
a.	I felt relieved about being more certain.	1	2	3	4	5	-8	B19a_a.
b.	I felt I had been told what I knew all along.	1	2	3	4	5	-8	B19a_b.
c.	I did not believe the results.	1	2	3	4	5	-8	B19a_c.
d.	I felt guilty.	1	2	3	4	5	-8	B19a_d.
e.	I felt depressed.	1	2	3	4	5	-8	B19a_e.
f.	I felt worried about the future.	1	2	3	4	5	-8	B19a_f.
g.	I fell apart emotionally.	1	2	3	4	5	-8	B19a_g.
h.	I felt anxious.	1	2	3	4	5	-8	B19a_h.
i.	I felt angry.	1	2	3	4	5	-8	B19a_i.
j.	I did not feel very differently.	1	2	3	4	5	-8	B19a_j.
k.	[For those who have daughters]. I wanted my daughters to be tested as soon as possible.	1	2	3	4	5	-8	B19a_k.

6. I am going to read a list of comments made by people after they have received their genetic test results. When you hear each comment, think about your thoughts and feelings toward the test results in terms of you. Please tell me how often each of the comments was true for you since you have received your test results, with the choices of *Not at All*, *Rarely*, *Sometimes*, and *Often*.

(INTERVIEWER NOTE: "IT" in the following questions refers to "RECEIVING TEST RESULTS")

		Not at All	Rarely	Sometimes	Often	
a.	I thought about it when I didn't mean to.	0	1	3	5	B116a.
b.	I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	3	5	B116b.
c.	I tried to remove it from memory.	0	1	3	5	B116c.
d.	I had trouble falling asleep or staying asleep, because of pictures or thoughts about it that came into my mind.	0	1	3	5	B116d.
e.	I had waves of strong feelings about it.	0	1	3	5	B116e.
f.	I had dreams about it.	0	1	3	5	B116f.
g.	I stayed away from reminders of it.	0	1	3	5	B116g.
h.	I felt as if it hadn't happened or it wasn't real.	0	1	3	5	B116h.
i.	I tried not to talk about it.	0	1	3	5	B116i.
j.	Pictures about it popped into my mind.	0	1	3	5	B116j.
k.	Other things kept making me think about it.	0	1	3	5	B116k.
l.	I was aware that I still had a lot of feelings about it, but I didn't deal with them	0	1	3	5	B116l.
m.	I tried not to think about it.	0	1	3	5	B116m.
n.	Any reminder brought back feelings about it.	0	1	3	5	B116n.
o.	My feelings about it were kind of numb.	0	1	3	5	B116o.

Please answer the following two questions using a 1-5 scale, where 1=Not at All and 5=All the time

		Not At All			All The Time		
7	How often do you worry about developing breast cancer OR developing breast cancer again?	1	2	3	4	5	B27.
8.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B28.

Symptoms of Strain Section

LISTED BELOW ARE SOME SYMPTOMS OF STRAIN THAT PEOPLE SOMETIMES HAVE. Please listen to each one carefully and tell me the answer which best reflects how much that symptom has bothered you during the **PAST THREE MONTHS**. Please use the following scale: 1=Not at all, 2=A little, 3=Quite a bit, and 4=Extremely.

		<i>Not at all</i>	<i>A little</i>	<i>Quite a bit</i>	<i>Extremely</i>	
1.	Suddenly scared for no reason	1	2	3	4	K1.
2.	Feeling fearful	1	2	3	4	K2.
3.	Faintness, dizziness, or weakness	1	2	3	4	K3.
4.	Nervousness or shakiness inside	1	2	3	4	K4.
5.	Heart pounding or racing	1	2	3	4	K5.
6.	Trembling	1	2	3	4	K6.
7.	Feeling tense or keyed up	1	2	3	4	K7.
8.	Headaches	1	2	3	4	K8.
9.	Spells of terror or panic	1	2	3	4	K9.
10.	Feeling restless, can't sit still	1	2	3	4	K10.
11.	Feeling low in energy--slowed down	1	2	3	4	K11.
12.	Blaming yourself for things	1	2	3	4	K12.
13.	Crying easily	1	2	3	4	K13.
14.	Loss of sexual interest or pleasure	1	2	3	4	K14.
15.	Poor appetite	1	2	3	4	K15.
16.	Difficulty falling asleep, staying asleep	1	2	3	4	K16.
17.	Feeling hopeless about the future	1	2	3	4	K17.
19.	Feeling blue	1	2	3	4	K19.
19.	Feeling lonely	1	2	3	4	K19.
20.	Feeling trapped or caught	1	2	3	4	K20.
21.	Worrying too much about things	1	2	3	4	K21.
22.	Feeling no interest in things	1	2	3	4	K22.
23.	Thoughts of ending your life	1	2	3	4	K23.
24.	Feeling everything is an effort	1	2	3	4	K24.
25.	Feelings of worthlessness	1	2	3	4	K25.

26. Are the symptoms we just talked about related to your receiving your genetic test results?

Yes	No
1	5

K26

Open-ended Questions:

1. Do you feel you were given adequate information before receiving your genetic results? B117.

1a. Was there anything omitted that would have been helpful? B117a.

1b. What information was most helpful? B117b.

2. What was the most effective or helpful thing you did to cope during this process? B118.

3. Were there any things you did that were not helpful? What were they? B119.

4. Who has been the most helpful during this time? (Make a listing in order R gives you) B120.

1. _____	5. _____
2. _____	6. _____
3. _____	7. _____
4. _____	8. _____

4a. If the list has more than one person, Who has been most helpful? B120a.

4b. What did they do for you?

B120b.

5. Has there been anything someone did that was not helpful?

B121.

6. Are you currently Married or Living in a steady marriage-like relationship?

B122.

(1) ☐ Yes

(5) ☐ No (Skip to next page, question 9)

If YES and R has not yet discussed her spouse/partner's support:

7. What's the most helpful thing your spouse/partner has done or is doing for you?

B123.

8. What's the most helpful thing your spouse could do for you?

B124.

9. Is there anything you plan to do immediately with this information?

B125.

10. What would you tell someone who is contemplating genetic testing?

B126.

11. Do you have any regrets about getting this testing? If yes, what are they?

B127.

12. Are you the first person in your family to get testing?

B128.

13. Will you encourage your relatives to get genetic testing or discourage them from testing?

B129.

14. We are trying to get a better picture of this process. What is something I didn't ask you that I should have?

B130.

POST-RESULTS INTERVIEW--*Six Month Follow-Up*

INTERVIEWER: For the Introduction, Please include the following important points or read the script:

- Thank the subject again for her participation (We know we've asked a lot of her.)
- This interview is 6 months after receiving genetic test results.
- Repetition of Questions needed to compare results to our previous research and to other researchers.
- Remind subject that this interview is confidential and completely voluntary.
- Suggest that the subject may prefer to get a pen and paper to jot down the different scales that will be used.

We have asked you a lot of questions over the last several years while you were waiting for your genetic results. This interview is scheduled 6 months after you received genetic test results. We recognize that we asked many of these questions before. They are the "gold" standards in this kind of research and in order to compare our results with other researchers we need to ask them again. As you know, offering of genetic testing for breast and ovarian cancer is still relatively new and genetic counselors rely on research like this to plan services. We know that we've asked a lot of you. Thanks again for all your patience.

(1) ☐ Affected (0) ☐ Unaffected

For AFFECTED Subjects Only:

1. First of all...Before your own diagnosis of cancer (breast or ovarian), Did you believe that you were a member of a family at high risk for breast and ovarian cancer?

(1) ☐ Yes (5) ☐ No

N1

Researchers are always interested in stress.

Standardized measures of stressful life events have been established with 0 representing no stress and 100 representing the greatest stress. To give you some reference points, here are some examples:

Change in residence is assigned a stress score of 20

Pregnancy is 40

Death of a close family member is 63

Death of a spouse is 100

Keeping in mind the ratings I just mentioned:

2. How would you rate the stress of being a member of a family at increased risk of breast and ovarian cancer?

N2

Being a member of a high risk family _____

- | | |
|---|---|
| 3. UNAFFECTED:
Hypothetically.... | AFFECTED:
Thinking about when you were first diagnosed with cancer (breast or ovarian)... |
|---|---|

How would you rate the stress of being diagnosed with cancer?

Diagnosis of cancer _____

N3

4. Now, how would you rate the stress of receiving your test results? [By that, I only am referring to the time at which you actually received your results.]

Stress of receiving results _____

N4

5. When you signed up for the study and gave your blood sample, rate how stressful you thought receiving your test results would be?

Stress you had thought getting your test results WOULD be _____

N5

6. Some women tell us that the whole process of getting results went very smoothly, while others tell us that it was an ordeal. Women have been both pleased and annoyed by the information they received or did not receive, the way results were given - that sort of thing. Using our stress ratings, how would you rate the process you went through to get results?

Process to get results _____

N6

- 6a. What about the process has been stressful? Do you have any suggestions for how the process could be improved?

N6a

(more space over) _____

Next, we are interested in any recent events in your family related to cancer and risk for cancer. In the past 6 months...

7. To your knowledge, have any of your family members received genetic test results in the past 6 months? What is their relationship to you? Do you know if a mutation was found? Positive or Negative?

(1) ☐ Yes (5) ☐ No (Skip to Next Question)

Total # Received Results: _____

N8t

	Relationship to R:	Positive Mutation Found	Negative No Mutation Found	Don't Know
a.		1	0	-9
b.		1	0	-9
c.		1	0	-9

N8a

N8b

N8c

8. Have any family members declined receiving test results (in the past 6 months)?

(1) ☐ Yes (5) ☐ No (Skip to Next Question)

Total # Declined Results: _____

N9t

	Relationship to R:
a.	
b.	
c.	

N9a

N9b

N9c

9. Have any family members received a new diagnosis of cancer (in the past 6 months)?

(1) ☐ Yes (5) ☐ No (Skip to Next Question)

Total # New Diagnosis: _____

N10t

	Relationship to R:
a.	
b.	
c.	

N10a

N10b

N10c

10. Have any family members had prophylactic surgery (in the past 6 months)?

(1) ☐ Yes (5) ☐ No (Skip to Next Question)

Total # Prophylactic Surgery: _____

N11

	Relationship to R:	Prophylactic Procedure:	
a.			N11a
b.			N11b
c.			N11c

11. Have any family members had any other things happen related to cancer or risk of cancer (in the past 6 months)? [such as treatment, surgery, or death?]

(1) ☐ Yes (5) ☐ No (Skip to Next Question)

Total # Family Members with a Cancer Related Event: _____

N12

	Relationship to R:	Event related to cancer:	
a.			N12a
b.			N12b
c.			N12c

12. Using a 5 point scale where 1=Not at All, 2-Rarely, 3=Sometimes, 4=Often, and 5=A Lot, Could you please tell us how often you talk with the following people in your family? If you have more than one close relative in a category, please answer the question thinking about the relative with whom you talk most frequently. How often do you talk with your _____ ?

		Not at All	Rarely	Sometimes	Often	A Lot	Not Applicable	
a.	Spouse	1	2	3	4	5	-8	N28a
b.	Daughter	1	2	3	4	5	-8	N28b
c.	Son	1	2	3	4	5	-8	N28c
d.	Mother	1	2	3	4	5	-8	N28d
e.	Grandmother	1	2	3	4	5	-8	N28e
f.	Sister	1	2	3	4	5	-8	N28f
g.	Aunt	1	2	3	4	5	-8	N28g
h.	Cousin	1	2	3	4	5	-8	N28h

13. Using the same scale, How often do you talk with each of these same people when something important and/or difficult happens in your life?

		Not at All	Rarely	Sometimes	Often	A Lot	Not Applicable	
a.	Spouse	1	2	3	4	5	-8	N29a
b.	Daughter	1	2	3	4	5	-8	N29b
c.	Son	1	2	3	4	5	-8	N29c
d.	Mother	1	2	3	4	5	-8	N29d
e.	Grandmother	1	2	3	4	5	-8	N29e
f.	Sister	1	2	3	4	5	-8	N29f
g.	Aunt	1	2	3	4	5	-8	N29g
h.	Cousin	1	2	3	4	5	-8	N29h

14. Before you actually got your results, How often did you discuss getting genetic testing for breast and ovarian cancer with these family members?

		Not at All	Rarely	Sometimes	Often	A Lot	Not Applicable	
a.	Spouse	1	2	3	4	5	-8	N30a
b.	Daughter	1	2	3	4	5	-8	N30b
c.	Son	1	2	3	4	5	-8	N30c
d.	Mother	1	2	3	4	5	-8	N30d
e.	Grandmother	1	2	3	4	5	-8	N30e
f.	Sister	1	2	3	4	5	-8	N30f
g.	Aunt	1	2	3	4	5	-8	N30g
h.	Cousin	1	2	3	4	5	-8	N30h

15. In the last six months since you received your genetic test results, How often have you discussed the results with each of them?

		Not at All	Rarely	Sometimes	Often	A Lot	Not Applicable	
a.	Spouse	1	2	3	4	5	-8	N31a
b.	Daughter	1	2	3	4	5	-8	N31b
c.	Son	1	2	3	4	5	-8	N31c
d.	Mother	1	2	3	4	5	-8	N31d

		Not at All	Rarely	Sometimes	Often	A Lot	Not Applicable	
e.	Grandmother	1	2	3	4	5	-8	N31e
f.	Sister	1	2	3	4	5	-8	N31f
g.	Aunt	1	2	3	4	5	-8	N31g
h.	Cousin	1	2	3	4	5	-8	N31h

16. Overall, to what extent do your family members talk about themselves as being a family at high risk for breast or ovarian cancer?

N32

Not at All	Rarely	Sometimes	Often	A Lot
1	2	3	4	5

Related Comments:

17. When you catch-up on what's going on in your family, to what extent are people's experiences with breast or ovarian cancer a topic of conversation?

N33

Not at All	Rarely	Sometimes	Often	A Lot
1	2	3	4	5

Related Comments:

18. In your family, to what extent do you agree on how to manage risk for breast or ovarian cancer? N34

Not at All	Rarely	Sometimes	Often	A Lot
1	2	3	4	5

Can you give me some examples of ways this comes up? _____

Have there been any disagreements about managing risk for cancer in your family? Can you tell me about that? _____

For those receiving uninformative results (No BRCA1 and BRCA2 Alterations Found AND No one in their family has a BRCA1 or BRCA2 alteration even though there is a family history of breast cancer) :

19. Even though no alteration was found for BRCA1 and BRCA2, Do you believe there is a possibility that you have another altered gene conveying an increased risk for breast and ovarian cancer?

(1) ☐ Yes (5) ☐ No

N13

20. If it becomes available, do you intend to get testing for any additional genes related to risk of breast and ovarian cancer?

(1) ☐ Yes (5) ☐ No (3) ☐ Unsure

N14

Now I want to ask you about the impact receiving results had on you. I'm going to ask you to rate the effect that getting your genetic results has had on different areas in your life. Using a scale of 1-5, 1=Very Negative Effect, 2=Somewhat Negative Effect, 3=No Effect, 4=Somewhat Positive Effect, and 5=Very Positive Effect...

21. On the whole, what effect has testing had on your life?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect
1	2	3	4	5

N15

22. Think about your everyday family life. What effect would you say getting the genetic test results has had?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect
1	2	3	4	5

N16

23. What effect has getting your results had on your work in and outside of the home?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect
1	2	3	4	5

N17

24. What effect has getting your results had on your concerns for your child's/children's future?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect
1	2	3	4	5

N19

25. Has getting these results changed the likelihood that you will have (more) children?

No/Fewer Children	No Change	More Children
1	2	3

N22

26. How has it affected your anxiety about the future?

Less Anxiety	No Change	More Anxiety
1	2	3

N18

27. Are there any OTHER areas that testing has affected?

N20

(1) ☐ Yes (5) ☐ No

27a. Please List Other Areas Affected by Genetic testing:

N20a

(more space over)

Now using a different scale of 1-5, 1=Not at All, 2=A Little, 3=Some, 4=Quite a Bit, and 5=Very Much...

28. How much has getting test results changed your health care decision(s)?

Not At All	A Little	Some	Quite a Bit	Very Much
1	2	3	4	5

N21

29. In general, how much has getting genetic results changed your life?

Not At All	A Little	Some	Quite a Bit	Very Much
1	2	3	4	5

N23

Symptoms of Strain Section

I'm going to be reading you some Symptoms Of Strain that people sometimes have. Please listen to each one carefully and tell me the answer which best reflects how much that symptom has **BOTHERED** you during the **PAST THREE MONTHS**. Please use the following scale: 1=Not at all, 2=A little, 3=Quite a bit, and 4=Extremely.

		<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Extremely</u>
1.	Suddenly scared for no reason	1	2	3	4
2.	Feeling fearful	1	2	3	4
3.	Faintness, dizziness, or weakness	1	2	3	4
4.	Nervousness or shakiness inside	1	2	3	4
5.	Heart pounding or racing	1	2	3	4
6.	Trembling	1	2	3	4
7.	Feeling tense or keyed up	1	2	3	4
8.	Headaches	1	2	3	4
9.	Spells of terror or panic	1	2	3	4
10.	Feeling restless, can't sit still	1	2	3	4

K1.

K2.

K3.

K4.

K5.

K6.

K7.

K8.

K9.

K10.

		<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Extremely</u>	
11.	Feeling low in energy--slowed down	1	2	3	4	K11.
12.	Blaming yourself for things	1	2	3	4	K12.
13.	Crying easily	1	2	3	4	K13.
14.	Loss of sexual interest or pleasure	1	2	3	4	K14.
15.	Poor appetite	1	2	3	4	K15.
16.	Difficulty falling asleep, staying asleep	1	2	3	4	K16.
17.	Feeling hopeless about the future	1	2	3	4	K17.
18.	Feeling blue	1	2	3	4	K18.
19.	Feeling lonely	1	2	3	4	K19.
20.	Feeling trapped or caught	1	2	3	4	K20.
21.	Worrying too much about things	1	2	3	4	K21.
22.	Feeling no interest in things	1	2	3	4	K22.
23.	Thoughts of ending your life	1	2	3	4	K23.
24.	Feeling everything is an effort	1	2	3	4	K24.
25.	Feelings of worthlessness	1	2	3	4	K25.

K26. To what extent are these current symptoms a result of getting genetic testing?

Not At All	A Little	Some	Quite a Bit	Very Much
1	2	3	4	5

K26

The following questions are about any counseling or psychotherapy you have received in the past, either related to cancer issues or other personal issues.

30. Have you ever seen any kind of counselor, therapist, psychologist, psychiatrist, or any other person like that for personal or emotional problems? (ASK the following probes as necessary: What type of person did you see? Why did you go? Have you ever seen someone for cancer issues? For dealing with Genetic Testing?)

Outpatient psychiatric or psychological treatment or counseling in the past 12 months:

- Exclude Educational Sessions with a Genetic Counselor
- Include treatment in outpatient and day hospital settings
- guidance or vocational counseling = No
- Axis I-type symptoms, even if not diagnosed = 3
- bereavement counseling = 4
- didactic analysis or equivalent ONLY for training/education = 8
- Family therapy ONLY to help a family member (subject did not discuss his/her own problems) = 8

Code all reasons that apply Next Page

CODE ALL REASONS THAT APPLY:

- | | | |
|---|---|------|
| a | <input type="checkbox"/> NO (Skip to Question N25) | N24a |
| b | <input type="checkbox"/> YES - Depression | N24b |
| c | <input type="checkbox"/> YES - Other Psychiatric (Axis I) | N24c |
| d | <input type="checkbox"/> YES - Interpersonal, Behavioral, Stress, Family, Developmental, etc. | N24d |
| e | <input type="checkbox"/> YES - Cancer Issues (diagnosis) | N24e |
| f | <input type="checkbox"/> YES - Genetic Testing Issues | N24f |
| g | <input type="checkbox"/> YES - Other (Specify Next page) _____ | N24g |

Specify treatment(s) and problem(s) _____

31. Are you currently seeing any kind of counselor, therapist, psychologist, psychiatrist, or any other person like that for personal or emotional problems? (ASK the following probes as necessary: What type of person are you seeing? Why are you going? Are you seeing someone for cancer issues? For dealing with Genetic Testing?)

Outpatient psychiatric or psychological treatment or counseling in the past 12 months:

- Exclude Educational Sessions with a Genetic Counselor
- Include treatment in outpatient and day hospital settings
- guidance or vocational counseling = No
- Axis I-type symptoms, even if not diagnosed = 3
- bereavement counseling = 4
- didactic analysis or equivalent ONLY for training/education = 8
- Family therapy ONLY to help a family member (subject did not discuss his/her own problems) = 8

CODE ALL REASONS THAT APPLY:

- | | | |
|---|---|------|
| a | <input type="checkbox"/> NO (Skip to Question N26) | N25a |
| b | <input type="checkbox"/> YES - Depression | N25b |
| c | <input type="checkbox"/> YES - Other Psychiatric (Axis I) | N25c |
| d | <input type="checkbox"/> YES - Interpersonal, Behavioral, Stress, Family, Developmental, etc. | N25d |
| e | <input type="checkbox"/> YES - Cancer Issues (diagnosis) | N25e |
| f | <input type="checkbox"/> YES - Genetic Testing Issues | N25f |
| g | <input type="checkbox"/> YES - Other (Specify) _____ | N25g |

Specify treatment(s) and problem(s) _____

32. Have you ever taken medication for emotional distress, depression, or anxiety?

(1) ☐ Yes (Record Meds below)

(5) ☐ No (Skip to Score Hopkins)

N26

33. What medication(s) did you take? How long did you take this medication? Are you still taking this medication? Were the reasons for starting this medication related to your cancer or your risk for cancer? Were the reasons for starting this medication related to your genetic testing or receiving genetic test results?

Medications for emotional distress, depression, or anxiety:

- Include St. John's Wart

- Exclude Hormonal Treatment and other herbs

	Medication:	Code:	Duration (Months)	Currently Taking?	Related to Cancer ?	Related to Genetic Testing?	
a.				(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	N27a
b.				(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	N27b
c.				(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	N27c
d.				(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	N27d
e.				(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	N27e
f.				(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	(1) <input type="checkbox"/> Yes (5) <input type="checkbox"/> No	N27f

INTERVIEWER: Go back to Score Hopkins-25 (Symptoms of Strain Section, p. 8) by adding up the numbered answers for K1-K25:

Score _____

If score = "44 or more," Complete SCID modules

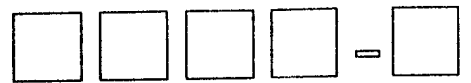
SCID Completed

If score = "43 or less," Skip SCID modules

☐

WHEN FINISHED WITH INTERVIEW BE SURE TO TELL SUBJECT:

- We have a short questionnaire that we will mail in about a week with some different questions.
- We'd like to contact everyone (one last time) in about 6 months, if that is okay.
- Check Address
- Thank subject.



WOMEN'S HEALTH STUDY

Post-Results Questionnaire
6 Month Follow-Up

TODAY'S DATE _____

ID _____

POST-RESULTS.2 QUESTIONNAIRE--Six Month Follow-Up

Genetic Testing Section

First, we would like to ask some questions about your reactions to receiving your genetic test results and their impact on your life.

1. How distressed were you when you received your genetic test results?

Not At All Distressed				Very Distressed
1	2	3	4	5

B69b

2. Overall, do you regret the decision to obtain your results?

Not At All				Very Much So
1	2	3	4	5

B71a

3. We are interested in the decisions women make after being notified of the results of their testing. *After* obtaining your results, are you now considering any of these options? Please circle only one response for each option.

		Done Before Obtaining Results	Definitely Will NOT Do	Probably Will NOT Do	Probably Will Do	Definitely Will Do	Done After Obtaining Results	Does Not Apply to Me
a.	Prophylactic Oophorectomy	0	1	2	3	4	5	-8
b.	Prophylactic Mastectomy	0	1	2	3	4	5	-8
c.	Monthly Breast Self-Exams	0	1	2	3	4	5	-8
d.	Yearly Physical Exams	0	1	2	3	4	5	-8
e.	Mammograms at least once a year	0	1	2	3	4	5	-8
f.	Encouraging my relatives to be tested	0	1	2	3	4	5	-8
g.	Discouraging my relatives from being tested	0	1	2	3	4	5	-8
h.	Telling some of my relatives what my results were	0	1	2	3	4	5	-8

B103a

B103b

B103c

B103d

B103e

B103f

B103g

B103h

4. For each of the following areas of your life, please indicate how much these decisions/plans have been affected by the results of genetic testing?

		<i>Not at all Affected</i>					<i>Very Much Affected</i>	<i>Not Applicable</i>	
		1	2	3	4	5		-8	
a.	Decisions about having children	1	2	3	4	5		-8	B35c
b.	Decisions about forms of birth control	1	2	3	4	5		-8	B36c
c.	Decisions about which steps to take to prevent breast cancer	1	2	3	4	5		-8	B37c
d.	Decisions about work and career	1	2	3	4	5		-8	B38c
e.	Decisions about savings and financial planning	1	2	3	4	5		-8	B39c
f.	Plans for your future	1	2	3	4	5		-8	B40c
g.	Plans for your daughter's future	1	2	3	4	5		-8	B42c

5. [Now that you have received genetic results and have more information about your risk of developing breast or ovarian cancer,] After receiving your genetic test results, how likely do you think you are to develop breast or ovarian cancer (or develop breast or ovarian cancer again), compared to **the average woman**? (Please circle one) B7a

Much Less Likely			Much More Likely	
1	2	3	4	5

6. After receiving your genetic test results, how likely do you think you are to develop breast or ovarian cancer (or develop breast or ovarian cancer again), compared to **the women in your family**? (Please circle one) B8a

Much Less Likely			Much More Likely	
1	2	3	4	5

7. Overall, what do you believe your risk to be of developing breast or ovarian cancer (or developing breast or ovarian cancer again) **in the near future**? B6

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
0	1	2	3	4	5	6	7	8	9	10

8. Overall, what do you believe your risk to be of developing breast or ovarian cancer (or developing breast or ovarian cancer again) **at some point in your lifetime?** B7

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
0	1	2	3	4	5	6	7	8	9	10

9. Now, we would like to ask you some questions about worries you may or may not experience.

		<i>Not At All</i>				<i>All The Time</i>	
a.	How often do you worry about developing breast cancer or developing breast cancer again?	1	2	3	4	5	B27
b.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B28
c.	How often do you worry about developing ovarian cancer or developing ovarian cancer again?	1	2	3	4	5	B110
d.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B111
e.	How often do you worry about your relatives developing breast or ovarian cancer?	1	2	3	4	5	B106
f.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B107
g.	How often do you worry about your relatives having an altered gene associated with risk for breast and ovarian cancer?	1	2	3	4	5	B108
h.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B109

Coping Section

1. How confident are you that **you** are coping effectively after getting your genetic test results?

<i>Not At All Confident</i>						<i>Very Confident</i>
1	2	3	4	5	6	7

B48e

2. How confident are you that **your family members** are coping effectively with the results of your genetic testing?

Not At All Confident						Very Confident
1	2	3	4	5	6	7

B48f

3. Sometimes people can find unexpected benefits in difficulties. We are interested in the ways in which you might have made positive use of genetic test results. For each of the statements below, indicate the degree to which your life has been affected positively by finding out your results.

		Not At All	A Very Small Degree	A Small Degree	A Moderate Degree	A Great Degree	A Very Great Degree	
a.	My priorities about what is important in life.	1	2	3	4	5	6	L6a
b.	I'm more likely to try to change things which need changing.	1	2	3	4	5	6	L6b
c.	An appreciation for the value of my own life.	1	2	3	4	5	6	L6c
d.	A feeling of self-reliance.	1	2	3	4	5	6	L6d
e.	A better understanding of spiritual matters.	1	2	3	4	5	6	L6e
f.	Knowing that I can count on people in times of troubles.	1	2	3	4	5	6	L6f
g.	A sense of closeness with others.	1	2	3	4	5	6	L6g
h.	Knowing I can handle difficulties.	1	2	3	4	5	6	L6h
i.	A willingness to express my emotions.	1	2	3	4	5	6	L6i
j.	Being able to accept the way things work out.	1	2	3	4	5	6	L6j
k.	Appreciating each day.	1	2	3	4	5	6	L6k
l.	Having compassion for others.	1	2	3	4	5	6	L6l
m.	I'm able to do better things with my life.	1	2	3	4	5	6	L6m

		<i>Not At All</i>	<i>A Very Small Degree</i>	<i>A Small Degree</i>	<i>A Moderate Degree</i>	<i>A Great Degree</i>	<i>A Very Great Degree</i>	
n.	New opportunities are available which wouldn't have been otherwise.	1	2	3	4	5	6	L6n
o.	Putting effort into my relationships.	1	2	3	4	5	6	L6o
p.	I have a stronger religious faith.	1	2	3	4	5	6	L6p
q.	I discovered that I'm stronger than I thought I was.	1	2	3	4	5	6	L6q
r.	I learned a great deal about how wonderful people are.	1	2	3	4	5	6	L6r
s.	I developed new interests.	1	2	3	4	5	6	L6s
t.	I accept needing others.	1	2	3	4	5	6	L6t
u.	I established a new path for my life.	1	2	3	4	5	6	L6u

5. Below is a list of comments made by people after they have received their genetic test results. When you read each comment, think about your thoughts and feelings toward the test results. Please indicate how often each of the comments was true for you since you received your test results, with the choices of *Not at All*, *Rarely*, *Sometimes*, and *Often*.

“IT” in the following questions refers to “RECEIVING YOUR TEST RESULTS”		Not at All	Rarely	Sometimes	Often	
a.	I thought about it when I didn't mean to.	0	1	3	5	B116a
b.	I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	3	5	B116b
c.	I tried to remove it from memory.	0	1	3	5	B116c
d.	I had trouble falling asleep or staying asleep, because of pictures or thoughts about it that came into my mind.	0	1	3	5	B116d
e.	I had waves of strong feelings about it.	0	1	3	5	B116e
f.	I had dreams about it.	0	1	3	5	B116f
g.	I stayed away from reminders of it.	0	1	3	5	B116g

**"IT" in the following questions refers to
"RECEIVING YOUR TEST RESULTS")**

		Not at All	Rarely	Sometimes	Often	
h.	I felt as if it hadn't happened or it wasn't real.	0	1	3	5	B116h
i.	I tried not to talk about it.	0	1	3	5	B116i
j.	Pictures about it popped into my mind.	0	1	3	5	B116j
k.	Other things kept making me think about it.	0	1	3	5	B116k
l.	I was aware that I still had a lot of feelings about it, but I didn't deal with them	0	1	3	5	B116l
m.	I tried not to think about it.	0	1	3	5	B116r
n.	Any reminder brought back feelings about it.	0	1	3	5	B116n
o.	My feelings about it were kind of numb.	0	1	3	5	B116o

Mood Section

1. In the past 6 months, have you had two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun? I12

(1) ☐ Yes (5) ☐ No (Skip to Health Section, Next Page)

- 1a. During this period, did your work or relationships suffer? I12a
(1) ☐ Yes (5) ☐ No

- 1b. During this period, did you get counseling or psychotherapy? I12b
(1) ☐ Yes (5) ☐ No

- 1c. During this period, did you get medication for this condition? I12c
(1) ☐ Yes (5) ☐ No

Health Section

1. How often do you usually get a mammogram?

B32a

- 1 ☐ Never (I have never had a mammogram).
- 2 ☐ Less than Once a Year
- 3 ☐ Once a Year
- 4 ☐ More than Once a Year
- 8 ☐ Does Not Apply because of surgery

2. How often do you perform self-examination of your breasts?

B33a

- 1 ☐ Never or rarely
- 2 ☐ Less than Once a Month
- 3 ☐ Monthly
- 4 ☐ More than Once a Month
- 8 ☐ Does Not Apply because of surgery

3. How often do you get CA-125 screening for ovarian cancer?

B33b

- 1 ☐ Never (I have never had a CA-125 screening).
- 2 ☐ Less than Once a Year
- 3 ☐ Once a Year
- 4 ☐ More than Once a Year
- 8 ☐ Does Not Apply because of surgery

4. How often do you get ultrasound screening for ovarian cancer?

B33c

- 1 ☐ Never (I have never had an ovarian ultrasound for cancer screening).
- 2 ☐ Less than Once a Year
- 3 ☐ Once a Year
- 4 ☐ More than Once a Year
- 8 ☐ Does Not Apply because of surgery

5. Has knowing your genetic results affected your **motivation** to perform breast self examination as frequently as needed?

Decreased Motivation		No Effect		Increased Motivation	Does Not Apply because of surgery
1	2	3	4	5	-8

B34d

6. Has knowing your genetic results affected your **confidence** that you will perform breast self examination as frequently as needed?

Decreased Confidence		No Effect		Increased Confidence	Does Not Apply because of surgery
1	2	3	4	5	-8

B34e

7. Has knowing your genetic results affected your **confidence** that you will perform breast self examination as **carefully and competently** as needed?

Decreased Confidence		No Effect		Increased Confidence		Does Not Apply because of surgery
1	2	3	4	5	-8	

B34f

8. How confident are you that you would be able to detect a change in your breasts using breast self examination?

Not At All						Very Much So	Does Not Apply because of surgery
1	2	3	4	5	6	7	-8

B34c

9. In general, would you say your health is:

1 ☐ Excellent 2 ☐ Very Good 3 ☐ Good 4 ☐ Fair 5 ☐ Poor

11

10. Compared to one year ago, how would you rate your health in general now? (Please Check One) 12

- 1 ☐ Much better now than one year ago
 2 ☐ Somewhat better now than one year ago
 3 ☐ About the same as one year ago
 4 ☐ Somewhat worse now than one year ago
 5 ☐ Much worse than one year ago

11. **During the past 4 weeks**, have you had any of the following problems with your work or other regular daily activities as a result of any **emotional** problems (such as feeling depressed or anxious)?

		Yes	No
a.	Cut down the amount of time you spent on work or other activities.	1	5
b.	Accomplished less than you would like.	1	5
c.	Didn't do work or other activities as carefully as usual.	1	5

15a

15b

15c

12. **During the past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

16

1 ☐ Not at all 2 ☐ Slightly 3 ☐ Moderately 4 ☐ Quite a bit 5 ☐ Extremely

13. How much bodily pain have you had **during the past 4 weeks**?

17

1 ☐ None 2 ☐ Very Mild 3 ☐ Mild 4 ☐ Moderate 5 ☐ Severe 6 ☐ Very Severe

14. **During the past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

18

1 ☐ Not at all 2 ☐ Slightly 3 ☐ Moderately 4 ☐ Quite a bit 5 ☐ Extremely

15. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks: Please mark the appropriate box to indicate your response.

		<i>All of the time</i>	<i>Most of the time</i>	<i>A good bit of the time</i>	<i>Some of the time</i>	<i>A little of the time</i>	<i>None of the time</i>	
a.	Did you feel full of pep?	1	2	3	4	5	6	I9a
b.	Have you been a very nervous person?	1	2	3	4	5	6	I9b
c.	Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6	I9c
d.	Have you felt calm and peaceful?	1	2	3	4	5	6	I9d
e.	Did you have a lot of energy?	1	2	3	4	5	6	I9e
f.	Have you felt downhearted and blue?	1	2	3	4	5	6	I9f
g.	Did you feel worn out?	1	2	3	4	5	6	I9i
h.	Have you been a happy person?	1	2	3	4	5	6	I9g
i.	Did you feel tired?	1	2	3	4	5	6	I9h

16. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

I10

- 1 ☐ All of the time
 2 ☐ Most of the time
 3 ☐ Some of the time
 4 ☐ A little of the time
 5 ☐ None of the time

17. How TRUE or FALSE is each of the following statements for you?

		<i>Definitely True</i>	<i>Mostly True</i>	<i>Don't Know</i>	<i>Mostly False</i>	<i>Definitely False</i>	
a.	I seem to get sick a little easier than other people.	1	2	3	4	5	I11a
b.	I am as healthy as anybody I know.	1	2	3	4	5	I11b
c.	I expect my health to get worse.	1	2	3	4	5	I11c
d.	My health is excellent.	1	2	3	4	5	I11d

LIFE EVENTS SECTION

1. Have any of the following events happened to you in the past six months? D1(a-m)
(Check All That Apply)
- | | |
|---|---|
| <p>a. <input type="checkbox"/> You retired, were fired, or laid off from work.</p> <p>b. <input type="checkbox"/> You were unemployed and looking for work.</p> <p>c. <input type="checkbox"/> Your spouse retired, was fired, or laid off from work.</p> <p>d. <input type="checkbox"/> Your spouse was unemployed and looking for work.</p> <p>e. <input type="checkbox"/> You had problems with the police or court.</p> <p>f. <input type="checkbox"/> You got into serious financial difficulties.</p> | <p>g. <input type="checkbox"/> A close family member was seriously ill or injured.</p> <p>h. <input type="checkbox"/> You had a marital separation or divorce.</p> <p>i. <input type="checkbox"/> You had serious troubles with relatives or close friends.</p> <p>j. <input type="checkbox"/> Your spouse had troubles or difficulties with relatives or close friends.</p> <p>k. <input type="checkbox"/> A close family member died.</p> <p>l. <input type="checkbox"/> A close friend or relative died.</p> <p>m. <input type="checkbox"/> You were seriously ill or injured.</p> |
|---|---|

This last section deals with your views of cancer prevention and treatment.

1. To what extent do you agree with the following statements?

		Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree	
a.	In the next year, there will be dramatic breakthroughs in the <u>prevention</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7a
b.	In the next year, there will be dramatic breakthroughs in the <u>treatment</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7b
c.	In the next year, the length of <u>survival</u> after diagnosis of breast cancer will increase.	1	2	3	4	5	N7c
d.	In the next year, the length of <u>survival</u> after diagnosis of ovarian cancer will increase.	1	2	3	4	5	N7d

		Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree	
e.	In the next 5 years, there will be dramatic breakthroughs in the <u>prevention</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7e
f.	In the next 5 years, there will be dramatic breakthroughs in the <u>treatment</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7f
g.	In the next five years, the length of <u>survival</u> after diagnosis of breast cancer will increase.	1	2	3	4	5	N7g
h.	In the next five years, the length of <u>survival</u> after diagnosis of ovarian cancer will increase.	1	2	3	4	5	N7h
i.	In the future, all women will routinely receive genetic testing for risk of breast and ovarian cancer.	1	2	3	4	5	N7i

Thank You Very Much For Your Participation!

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WOMEN'S HEALTH STUDY

Post-Results Questionnaire #3
12 Month Follow-Up

TODAY'S DATE _____

ID _____

POST-RESULTS.3--12 Month Follow-Up

First of all, we would like to acknowledge that we are asking many of the same questions that we've asked before. This way we can better understand how your reactions have changed or have stayed the same over time.

Genetic Testing

1. How distressed were you when you received your genetic test results?

Not At All Distressed				Very Distressed
1	2	3	4	5

B69b

2. Overall, do you regret the decision to obtain your results?

Not At All				Very Much So
1	2	3	4	5

B71a

3. With your genetic test results, Are you now considering any of the following options?
Please circle only one response for each option.

		Done Before Obtaining Results	Definitely Will NOT Do	Probably Will NOT Do	Probably Will Do	Definitely Will Do	Done After Obtaining Results	Does Not Apply to Me
a.	Prophylactic Oophorectomy (ovaries removed)	0	1	2	3	4	5	-8
b.	Prophylactic Mastectomy	0	1	2	3	4	5	-8
c.	Monthly Breast Self-Exams	0	1	2	3	4	5	-8
d.	Yearly Physical Exams	0	1	2	3	4	5	-8
e.	Mammograms at least once a year	0	1	2	3	4	5	-8
f.	Encouraging my relatives to be tested	0	1	2	3	4	5	-8
g.	Discouraging my relatives from being tested	0	1	2	3	4	5	-8
h.	Telling some of my relatives what my results were	0	1	2	3	4	5	-8

B103a

B103b

B103c

B103d

B103e

B103f

B103g

B103h

4. For each of the following areas of your life, please indicate how much these decisions/plans have been affected by the results of genetic testing?

		<i>Not at all Affected</i>			<i>Very Much Affected</i>		<i>Not Applicable</i>	
		1	2	3	4	5	-8	
a.	Decisions about having children	1	2	3	4	5	-8	B35c
b.	Decisions about forms of birth control	1	2	3	4	5	-8	B36c
c.	Decisions about which steps to take to prevent breast cancer	1	2	3	4	5	-8	B37c
d.	Decisions about work and career	1	2	3	4	5	-8	B38c
e.	Decisions about savings and financial planning	1	2	3	4	5	-8	B39c
f.	Plans for your future	1	2	3	4	5	-8	B40c
g.	Plans for your daughter's future	1	2	3	4	5	-8	B42c

5. On the whole, what effect has testing had on your life?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect	
1	2	3	4	5	N15

6. Think about your everyday family life. What effect would you say getting the genetic test results has had?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect	
1	2	3	4	5	N16

7. What effect has getting your results had on your work in and outside of the home?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect	
1	2	3	4	5	N17

8. What effect has getting your results had on your concerns for your child's/children's future?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect
1	2	3	4	5

N19

9. Has getting these results changed the likelihood that you will have (more) children?

Yes, Will Have Fewer Children	No Change	Yes, Will Have More Children
1	2	3

N22

10. How has getting genetic testing affected your anxiety about the future?

Less Anxiety	No Change	More Anxiety
1	2	3

N18

11. Are there any OTHER areas of your life that testing has affected?

N20

(1) ☐ Yes (5) ☐ No

11a. Please List Other Areas of your life Affected by Genetic testing:

N20a

12. How much has getting test results changed your health care decision(s)?

Not At All	A Little	Some	Quite a Bit	Very Much
1	2	3	4	5

N21

12a. If applicable, How have your health care decisions changed?

13. In general, how much has getting genetic results changed your life?

Not At All	A Little	Some	Quite a Bit	Very Much
1	2	3	4	5

N23

13a. If applicable, How has your life changed?

14. Now, we would like to ask you some questions about worries you may or may not experience.

		<div>Not At All</div> <div>All The Time</div>					
a.	How often do you worry about developing breast cancer or developing breast cancer again?	1	2	3	4	5	B27
b.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B28
c.	How often do you worry about developing ovarian cancer or developing ovarian cancer again?	1	2	3	4	5	B110
d.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B111
e.	How often do you worry about your relatives developing breast or ovarian cancer?	1	2	3	4	5	B106
f.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B107
g.	How often do you worry about your relatives having an altered gene associated with risk for breast and ovarian cancer?	1	2	3	4	5	B108
h.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B109

Coping Section

1. How confident are you that **you** are coping effectively after getting your genetic test results?

Not At All Confident						Very Confident
1	2	3	4	5	6	7

B48e

2. How confident are you that **your family members** are coping effectively with the results of your genetic testing?

Not At All Confident						Very Confident
1	2	3	4	5	6	7

B48f

3. Below is a list of comments made by people after they have received their genetic test results. When you read each comment, think about your thoughts and feelings toward the test results. Please indicate how often each of the comments has been true for you since you received your test results, with the choices of *Not at All*, *Rarely*, *Sometimes*, and *Often*.

“IT” in the following questions refers to
“RECEIVING YOUR TEST RESULTS”)

		Not at All	Rarely	Sometimes	Often
a.	I thought about it when I didn't mean to.	0	1	3	5
b.	I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	3	5
c.	I tried to remove it from memory.	0	1	3	5
d.	I had trouble falling asleep or staying asleep, because of pictures or thoughts about it that came into my mind.	0	1	3	5
e.	I had waves of strong feelings about it.	0	1	3	5
f.	I had dreams about it.	0	1	3	5
g.	I stayed away from reminders of it.	0	1	3	5
h.	I felt as if it hadn't happened or it wasn't real.	0	1	3	5
i.	I tried not to talk about it.	0	1	3	5
j.	Pictures about it popped into my mind.	0	1	3	5

B116a

B116b

B116c

B116d

B116e

B116f

B116g

B116h

B116i

B116j

"**IT**" in the following questions refers to
"RECEIVING YOUR TEST RESULTS")

		Not at All	Rarely	Sometimes	Often	
k.	Other things kept making me think about it.	0	1	3	5	B116k
l.	I was aware that I still had a lot of feelings about it, but I didn't deal with them	0	1	3	5	B116l
m.	I tried not to think about it.	0	1	3	5	B116m
n.	Any reminder brought back feelings about it.	0	1	3	5	B116n
o.	My feelings about it were kind of numb.	0	1	3	5	B116o

Family Events

We would like to ask you if there were any recent events in your family related to cancer or risk for cancer.

1. To your knowledge, have any of your family members received genetic test results **in the past 6 months**? What is their relationship to you? Do you know if a mutation was found? Positive or Negative?

(1) ☐ Yes (5) ☐ No (Skip to Next Question)

Total # of Family Members who Received Results: _____

N8t

	Relationship to You:	Positive Mutation Found	Negative No Mutation Found	Don't Know	
a.		1	0	-9	N8a
b.		1	0	-9	N8b
c.		1	0	-9	N8c

2. Have any of your family members declined receiving test results **in the past 6 months**?

(1) ☐ Yes (5) ☐ No (Skip to Next Question)

Total # of Family Members who Declined Results: _____

N9t

	Relationship to You:	
a.		N9a
b.		N9b
c.		N9c

3. Have any family members received a new diagnosis of cancer **in the past 6 months?**

(1) ☐ Yes (5) ☐ No (Skip to Next Question)

Total # of Family Members who had a New Diagnosis of cancer : _____ N10t

	Relationship to You:	
a.		N10a
b.		N10b
c.		N10c

4. Have any family members had prophylactic surgery **in the past 6 months?**

(1) ☐ Yes (5) ☐ No (Skip to Next Question)

Total # of Family Members who had Prophylactic Surgery: _____ N11

	Relationship to You:	Prophylactic Procedure:	
a.			N11a
b.			N11b
c.			N11c

5. Have any family members had any other things happen related to cancer or risk of cancer **in the past 6 months?** [such as treatment, surgery, or death?]

(1) ☐ Yes (5) ☐ No (Skip to Next Question)

Total # Family Members with a Cancer Related Event: _____ N12

	Relationship to You:	Event related to cancer:	
a.			N12a
b.			N12b
c.			N12c

6. In the last six months, How often have you discussed your genetic results with each of the following family members?

		Not at All	Rarely	Sometimes	Often	A Lot	Not Applicable	
a.	Spouse	1	2	3	4	5	-8	N31a
b.	Daughter	1	2	3	4	5	-8	N31b
c.	Son	1	2	3	4	5	-8	N31c

		Not at All	Rarely	Sometimes	Often	A Lot	Not Applicable	
d.	Mother	1	2	3	4	5	-8	N31d
e.	Grandmother	1	2	3	4	5	-8	N31e
f.	Sister	1	2	3	4	5	-8	N31f
g.	Aunt	1	2	3	4	5	-8	N31g
h.	Cousin	1	2	3	4	5	-8	N31h

Health Section

1. How often do you usually get a mammogram? B32a

- 1 ☐ Never (I have never had a mammogram).
2 ☐ Less than Once a Year
3 ☐ Once a Year
4 ☐ More than Once a Year
-8 ☐ Does Not Apply because of surgery

2. How often do you perform self-examination of your breasts? B33a

- 1 ☐ Never or rarely
2 ☐ Less than Once a Month
3 ☐ Monthly
4 ☐ More than Once a Month
-8 ☐ Does Not Apply because of surgery

3. How often do you get CA-125 screening for ovarian cancer? B33b

- 1 ☐ Never (I have never had a CA-125 screening).
2 ☐ Less than Once a Year
3 ☐ Once a Year
4 ☐ More than Once a Year
-8 ☐ Does Not Apply because of surgery

4. How often do you get ultrasound screening for ovarian cancer? B33c

- 1 ☐ Never (I have never had an ovarian ultrasound for cancer screening).
2 ☐ Less than Once a Year
3 ☐ Once a Year
4 ☐ More than Once a Year
-8 ☐ Does Not Apply because of surgery

5. Has knowing your genetic results affected your **motivation** to perform breast self examination as frequently as needed?

Decreased Motivation		No Effect		Increased Motivation	Does Not Apply because of surgery
1	2	3	4	5	-8

B34d

6. Has knowing your genetic results affected your **confidence** that you will perform breast self examination as **frequently** as needed?

Decreased Confidence		No Effect		Increased Confidence	Does Not Apply because of surgery
1	2	3	4	5	-8

B34e

7. Has knowing your genetic results affected your **confidence** that you will perform breast self examination as **carefully and competently** as needed?

Decreased Confidence		No Effect		Increased Confidence	Does Not Apply because of surgery
1	2	3	4	5	-8

B34f

Symptoms of Strain Section

Listed below are some symptoms of strain that people sometimes have. Please read Each One Carefully And Circle The Answer Which Best Reflects How Much That Symptom Has **BOTHERED** you during the **PAST THREE MONTHS**. Please use the following scale: 1=Not at all, 2=A little, 3=Quite a bit, and 4=Extremely.

		<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Extremely</u>
1.	Suddenly scared for no reason	1	2	3	4
2.	Feeling fearful	1	2	3	4
3.	Faintness, dizziness, or weakness	1	2	3	4
4.	Nervousness or shakiness inside	1	2	3	4
5.	Heart pounding or racing	1	2	3	4
6.	Trembling	1	2	3	4
7.	Feeling tense or keyed up	1	2	3	4
8.	Headaches	1	2	3	4
9.	Spells of terror or panic	1	2	3	4
10.	Feeling restless, can't sit still	1	2	3	4
11.	Feeling low in energy--slowed down	1	2	3	4
12.	Blaming yourself for things	1	2	3	4
13.	Crying easily	1	2	3	4
14.	Loss of sexual interest or pleasure	1	2	3	4

K1.

K2.

K3.

K4.

K5.

K6.

K7.

K8.

K9.

K10.

K11.

K12.

K13.

K14.

		<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Extremely</u>	
15.	Poor appetite	1	2	3	4	K15.
16.	Difficulty falling asleep, staying asleep	1	2	3	4	K16.
17.	Feeling hopeless about the future	1	2	3	4	K17.
18.	Feeling blue	1	2	3	4	K18.
19.	Feeling lonely	1	2	3	4	K19.
20.	Feeling trapped or caught	1	2	3	4	K20.
21.	Worrying too much about things	1	2	3	4	K21.
22.	Feeling no interest in things	1	2	3	4	K22.
23.	Thoughts of ending your life	1	2	3	4	K23.
24.	Feeling everything is an effort	1	2	3	4	K24.
25.	Feelings of worthlessness	1	2	3	4	K25.

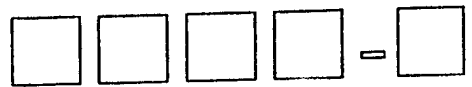
26. To what extent are these current symptoms a result of getting genetic testing?

Not At All	A Little	Some	Quite a Bit	Very Much
1	2	3	4	5

K26

Your Participation has been very much appreciated. Your contribution to the study of genetic testing for breast and ovarian cancer has been great. This is the last questionnaire for our study. A sincere thank you for hanging in with us over the past few years!

-Women's Health Study Staff



WOMEN'S HEALTH STUDY
Spouse/Partner Questionnaire

A-ID _____

BACKGROUND DATA SECTION

1. Date of Birth _____ Month _____ Day _____ Year A1.
2. Ethnic Background: White ☐ 1 Black ☐ 4 A2.
 Hispanic ☐ 2 Asian ☐ 5
 Native American ☐ 3 Other ☐ 6
3. Religion: Catholic ☐ 1 Protestant ☐ 4 A3.
 Jewish ☐ 2 Buddhist ☐ 5
 Muslim ☐ 3 Other ☐ 6
 None ☐ 7
- 3a. How often do you attend religious services? A3a.
☐ 1 Less Than Once a Month ☐ 5 A Few Times A Month or More
- 3b. How important are religious and spiritual beliefs in your life? A3b.
 Not at All Very Important
 1 2 3 4 5
4. Are you currently working for pay outside the home? Yes ☐ 1 No ☐ 5 A7.
5. If yes, about how many hours per week are you working for pay? A8.
Less than 10 10-20 21-30 31-40 41 or more
☐ ☐ ☐ ☐ ☐
(1) (2) (3) (4) (5)
6. What is the highest level of education you have completed? (Check one) A9.
1 ☐ Less than 9th grade 5 ☐ Completed college
2 ☐ Dropped out of high school 6 ☐ Some graduate or professional training
3 ☐ Completed high school 7 ☐ Completed graduate or professional training
4 ☐ Some college

7. What is your household's total income? (Check one)

(1) <input type="checkbox"/> Less than \$10,000	(4) <input type="checkbox"/> \$30,000 to \$39,999	(7) <input type="checkbox"/> \$60,000 to \$69,999
(2) <input type="checkbox"/> \$10,000 to \$19,999	(5) <input type="checkbox"/> \$40,000 to \$49,999	(8) <input type="checkbox"/> Greater than \$69,999
(3) <input type="checkbox"/> \$20,000 to \$29,999	(6) <input type="checkbox"/> \$50,000 to \$59,999	

- 1

PERSONAL ATTITUDES SECTION

1. For each of these statements, please indicate the extent to which you agree or disagree by circling the appropriate number. There are no right or wrong answers. We are only interested in your opinions.

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>		
		1	2	3	4	5	
a.	If you don't have your health, you don't have anything.						L5a.
b.	There are many things I care about more than my health.						L5b.
c.	Good health is of only minor importance in a happy life.						L5c.
d.	There is nothing more important than good health.						L5d.
e.	In uncertain times, I usually expect the best.						E1.
f.	It's easy for me to relax.						E2.
g.	If something can go wrong for me, it will.						E3.
h.	I always look on the bright side of things.						E4.
i.	I'm always optimistic about my future.						E5.
j.	I enjoy my friends a lot.						E6.
k.	It's important for me to keep busy.						E7.
l.	I hardly ever expect things to go my way.						E8.
m.	Things never work out the way I want them to.						E9.
n.	I don't get upset too easily.						E10.
o.	I'm a believer in the idea that "every cloud has a silver lining."						E11.
p.	I rarely count on good things happening to me.						E12.

HEALTH SECTION

The following questions concern your wife/partner's risk of developing breast cancer again and of her having the altered gene which has been found to be associated with increased risk for breast cancer. As you may know, breast cancer runs in certain families. In some of these families, persons who develop cancer have an altered version of a gene, BRCA1. Some family members will inherit the gene and others will not.

		<div style="display: flex; justify-content: space-between; width: 100%;"> <i>Not At All</i> <i>All The Time</i> </div>				
1.	How often do you worry about your wife/partner again developing breast cancer?	1	2	3	4	5
2.	To what extent do these worries interfere with your every day life?	1	2	3	4	5
3.	How often do you worry about your wife/partner having the altered gene associated with risk for breast cancer?	1	2	3	4	5
4.	To what extent do worries about your wife/partner having this altered gene interfere with your every day life?	1	2	3	4	5
5.	How often do you worry about developing cancer yourself?	1	2	3	4	5

B27.

B28.

B29.

B30.

B31.

6. How likely do you think your wife/partner is to develop breast cancer again in the near future? **(Please circle one).**

B9.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

7. Overall, what do you believe your wife/partner's risk is of developing breast cancer again at some point in her lifetime?

B10.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

8. Overall, what do you believe your wife/partner's risk is of developing some other cancer unrelated to breast cancer at some point in her lifetime?

B14.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

9. How often does your wife/partner express concern and seek support from you about the risk of breast cancer to herself and women in her family?

B49.

Never	Rarely	Sometimes	Often
1	2	3	4

10. How much of a burden is this on you?

B50.

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

11. How often do you discuss genetic testing for breast cancer with your wife/partner?

B51.

Never	Rarely	Sometimes	Often
1	2	3	4

12. When you have these discussions, who generally initiates them?

B52.

You	Your Wife/partner	Equally
1	2	3

13. How satisfied are you with these discussions?

B53.

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

14. How often do you and your wife/partner get into a disagreement or conflict over the issue of her getting genetic testing for the risk of breast cancer?

B54.

Never	Rarely	Sometimes	Often
1	2	3	4

15. Do you think it is beneficial to have genetic testing for risk of breast cancer available to women?

B55.

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

16. Do you want your wife/partner to get genetic testing for risk of breast cancer?

B56.

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

17. Overall, how much do you want your opinion to be taken into account in your wife/partner's decision **whether to be tested** for the breast cancer gene?

B57.

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

18. Overall, how much do you want your opinion to be taken into account in your wife/partner's decisions **about what to do about her risk** for breast cancer?

B58.

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

19. Overall, how important is your opinion in your wife/partner's decision whether to be tested for the altered gene carrying susceptibility to breast cancer?

B59.

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

- 19a. Do you believe your wife has the altered gene that increases the risk of breast cancer?

B60.

(1) ☐ Yes (5) ☐ No

- 19b. How confident are you in this belief?

Not At All Confident						Very Confident
1	2	3	4	5	6	7

B61.

20. Have you attended individual, family or group sessions to become informed about your wife/partner's risk for breast cancer and what can be done?

B62.

(1) ☐ Yes (5) ☐ No

21. How much contact have you had with medical personnel concerning her risk of cancer?

B63.

Very Little 1 2 3 4 5 6 A Lot 7

- 22a. Overall, do you feel you are adequately informed concerning your wife/partner's risk for cancer and what can be done about it? **B43a.**
- Not at All 1 2 3 4 5 6 7 Very Much
- 22b. Do you feel you are adequately informed about your wife/partner's risk for developing breast cancer **again**? **B43b.**
- Not at All 1 2 3 4 5 6 7 Very Much
- 22c. Do you feel you are adequately informed about the benefits and drawbacks of genetic testing for risk of breast cancer? **B44.**
- Not at All 1 2 3 4 5 6 7 Very Much
- 22d. Do you feel you are adequately informed about what your wife/partner could do personally to reduce her risk of breast cancer if she had the altered BRCA1 gene? **B45.**
- Not at All 1 2 3 4 5 6 7 Very Much
- 22e. Do you feel you are adequately informed about the benefits and drawbacks of options available to women who have the altered BRCA1 gene? **B46.**
- Not at All 1 2 3 4 5 6 7 Very Much
- 22f. Do you feel you are adequately informed about what it would mean for your children if your wife/partner had the altered BRCA1 gene? ☐ Check here if you do not have children. **B47.**
- (-8)
- Not at All 1 2 3 4 5 6 7 Very Much **C-22f.**
23. How confident are you that your wife/partner:
- 23a. Will make the best decision about whether to be tested for BRCA1, the altered gene associated with risk of breast cancer? **B48a.**
- Not at All 1 2 3 4 5 6 7 Very Much
- 23b. Would cope effectively with the finding that she had the altered BRCA1 gene? **B48b.**
- Not at All 1 2 3 4 5 6 7 Very Much

23. (continued) How confident are you that your wife/partner:

23c. Would make the best decision concerning her options if she were found to have the altered BRCA1 gene? B48c.

Not at All 2 3 4 5 6 7 Very Much

23d. Would be able to follow through with her decisions and cope effectively over the long haul if she were found to have the altered BRCA1 gene? B48d.

Not at All 2 3 4 5 6 7 Very Much

24. Please indicate the extent to which you agree or disagree with the following statements using the 1 (strongly disagree) to 5 (strongly agree) scale. Please try to provide your opinion for all of these questions. However, if you feel you simply do not know enough to have an opinion, check the "I don't know" box.

		Strongly Disagree			Strongly Agree		I Don't Know	
		1	2	3	4	5	9	
a.	Mammography is effective in the early detection of breast cancer in women.	1	2	3	4	5	9	B20a.
b.	Breast cancer that is detected early is curable.	1	2	3	4	5	9	B20b.
c.	Mammography can detect lumps that cannot be felt by a woman or by her doctor.	1	2	3	4	5	9	B20c.
d.	If more women went for breast screening, there would be fewer deaths from breast cancer.	1	2	3	4	5	9	B20d.
e.	If a lump is found in a woman's breast, it is usually too late to do anything about it.	1	2	3	4	5	9	B20f.
f.	There are so many things that could happen to someone's health that it is pointless for a woman to worry about breast cancer.	1	2	3	4	5	9	B20i.
g.	If a woman were found to have breast cancer, the chances of it being cured are high.	1	2	3	4	5	9	B20m.
h.	Once a woman has had effective treatment for breast cancer, she will not get it again.	1	2	3	4	5	9	B20n.
i.	A mastectomy totally eliminates a woman's risk for breast cancer.	1	2	3	4	5	9	B20o.
j.	All women who have the altered version of the BRCA1 gene will get breast cancer.	1	2	3	4	5	9	B20p.
k.	Most of the breast cancer in the United States is due to altered versions of the BRCA1 gene.	1	2	3	4	5	9	B20q.

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>		<i>I Don't Know</i>
		1	2	3	4	5	9
l.	The next decade is going to bring major advances in the detection and treatment of breast cancer.						
m.	Over the next decade, medical breakthroughs are going to make breast cancer much less of a threat to women's health.						

B20r.

B20s.

25. If your wife/partner were to take the test and find that she did not have the altered version of the BRCA1 gene which is associated with high risk for breast cancer, what would you expect your reactions to be?

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>	
		1	2	3	4	5
a.	I would feel wonderful.					
b.	I would feel I had been told what I knew all along.					
c.	I would feel relieved.					
d.	I would not believe the results.					
e.	I would fall apart emotionally.					
f.	I would feel guilty.					
g.	I would still feel anxious.					
h.	I would feel angry.					
i.	I would feel prepared for the future.					
j.	I would feel I had done all I needed to do.					
k.	I would not feel very differently.					

B18a.

B18b.

B18c.

B18d.

B18e.

B18f.

B18g.

B18h.

B18i.

B18j.

B18k.

26. If your wife/partner were to take the test and find out that she had the altered version of the BRCA1 gene for breast cancer, what would you expect your reactions to be?

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>	
		1	2	3	4	5
a.	I would feel relieved about being more certain.					
b.	I would feel I had been told what I knew all along.					
c.	I would not believe the results.					
d.	I would feel guilty.					
e.	I would feel depressed.					

B19a.

B19b.

B19c.

B19d.

B19e.

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>		
		1	2	3	4	5	
f.	I would feel worried about the future.	1	2	3	4	5	B19f.
g.	I would fall apart emotionally.	1	2	3	4	5	B19g.
h.	I would feel anxious.	1	2	3	4	5	B19h.
i.	I would feel angry.	1	2	3	4	5	B19i.
j.	I would not feel very differently.	1	2	3	4	5	B19j.
k.	I would want my daughters to be tested as soon as possible.	1	2	3	4	5	B19k.

27. The following questions concern your involvement in your wife/partner's health care:

		<i>Not at All</i>			<i>Very Often</i>		
		1	2	3	4	5	
a.	To what extent do you go with your wife/partner to her appointments with doctors?	1	2	3	4	5	H35a.
b.	To what extent do you talk with your wife/partner's doctor or other medical personnel about her risk of cancer?	1	2	3	4	5	H35b.
c.	To what extent do you keep track of what your wife/partner needs to do about her risk of cancer?	1	2	3	4	5	H35c.
d.	To what extent do you change your activities to look after your wife/partner?	1	2	3	4	5	H35d.

28. If my wife/partner were tested and found to have the altered BRCA1 gene carrying increased risk of breast cancer, I would want her to manage her risk by relying:

- a. Being extra careful about breast self-examination and regular medical examinations. **B64a.**

<i>Not at All</i>						<i>Very Much So</i>
1	2	3	4	5	6	7

- b. Getting preventive surgery. **B64b.**

<i>Not at All</i>						<i>Very Much So</i>
1	2	3	4	5	6	7

29. I do not believe it would be my place to tell my wife/partner my opinion about what she should do about her risk of breast cancer.

B65.

Strongly Disagree						Strongly Agree
1	2	3	4	5	6	7

RELATIONSHIPS

1. Is there anyone in your life with whom you can share your most private feelings without holding back? C21.
(1) ☐ Yes (5) ☐ No

2. Can you share your most private feelings with your wife/partner without holding back? C21a.
(1) ☐ Yes (5) ☐ No

3. Is there anyone besides your wife/partner with whom you can share your most private feelings without holding back? C21b.
(1) ☐ Yes (5) ☐ No

4. Have any of the events listed below happened to you in the past six months? D1 (a-m)
(Check All That Apply)

- | | |
|---|---|
| a. <input type="checkbox"/> You retired or were fired or laid off from work. | g. <input type="checkbox"/> A close family member was seriously ill or injured. |
| b. <input type="checkbox"/> You were unemployed and looking for work. | h. <input type="checkbox"/> You had a marital separation or divorce. |
| c. <input type="checkbox"/> Your spouse retired or was fired or laid off from work. | i. <input type="checkbox"/> You had serious troubles with relatives or close friends. |
| d. <input type="checkbox"/> Your spouse was unemployed and looking for work. | j. <input type="checkbox"/> Your spouse had troubles with relatives or close friends. |
| e. <input type="checkbox"/> You had problems with the police or court. | k. <input type="checkbox"/> A close family member died. |
| f. <input type="checkbox"/> You got into serious financial difficulties. | l. <input type="checkbox"/> A close friend or relative died. |
| | m. <input type="checkbox"/> You were seriously ill or injured. |

MARRIAGE SECTION

Most people have disagreements in their relationships. Please indicate, using check marks the extent of agreement or disagreement experienced between you and your wife/partner on the following issues **DURING THE PAST MONTH.**

		<i>Always Agree</i>	<i>Almost Always Agree</i>	<i>Occa- sionally Disagree</i>	<i>Fre- quently Disagree</i>	<i>Almost Always Disagree</i>	<i>Always Disagree</i>
1.	Handling family finances	1	2	3	4	5	6
2.	Matters of recreation	1	2	3	4	5	6
3.	Religious matters	1	2	3	4	5	6
4.	Demonstration of affection	1	2	3	4	5	6
5.	Friends	1	2	3	4	5	6
6.	Sex relations	1	2	3	4	5	6
7.	Conventionality (correct or proper behavior)	1	2	3	4	5	6
8.	Philosophy of life	1	2	3	4	5	6
9.	Ways of dealing with parents or in-laws	1	2	3	4	5	6
10.	Aims, goals, and things believed important	1	2	3	4	5	6
11.	Amount of time spent together	1	2	3	4	5	6
12.	Making major decisions	1	2	3	4	5	6
13.	Household tasks	1	2	3	4	5	6
14.	Leisure time interests and activities	1	2	3	4	5	6
15.	Career decisions	1	2	3	4	5	6

H1.

H2.

H3.

H4.

H5.

H6.

H7.

H8.

H9.

H10.

H11.

H12.

H13.

H14.

H15.

		<i>All of the Time</i>	<i>Most of the Time</i>	<i>More Often than Most</i>	<i>Occa- sionally</i>	<i>Rarely</i>	<i>Never</i>
16.	How often do you discuss or have you considered divorce, separation, or terminating your relationship?	1	2	3	4	5	6
17.	How often do you or your wife/partner leave the house after a fight?	1	2	3	4	5	6
18.	In general, how often do you think that things between you and your wife/partner are going well?	1	2	3	4	5	6
19.	Do you confide in your wife/partner?	1	2	3	4	5	6
20.	Do you ever regret that you married (or lived together)?	1	2	3	4	5	6
21.	How often do you and your wife/partner quarrel?	1	2	3	4	5	6
22.	How often do you and your wife/partner "get on each other's nerves?"	1	2	3	4	5	6

H16.

H17.

H18.

H19.

H20.

H21.

H22.

		<i>Every Day</i>	<i>Almost Every Day</i>	<i>Occa- sionally</i>	<i>Rarely</i>	<i>Never</i>
23.	Do you kiss your wife/partner?	1	2	3	4	5

H23.

		<i>All of Them</i>	<i>Most of Them</i>	<i>Some of Them</i>	<i>Very few of Them</i>	<i>None of Them</i>
24.	Do you and your wife/partner engage in outside interests together?	1	2	3	4	5

H24.

33. Considering **only the positive feelings** you have toward your wife/partner, and **ignoring the negative ones**, please rate how positive these feelings are:

H33.

Not At All Positive									Extremely Positive
1	2	3	4	5	6	7	8	9	10

34. Considering **only the negative feelings** you have toward your wife/partner, and **ignoring the positive ones**, please rate how negative these feelings are:

H34.

Not At All Negative									Extremely Negative
1	2	3	4	5	6	7	8	9	10

CURRENT FAMILY SECTION

Please indicate the extent to which each of the following items describes your current family (your household).

		Strongly Disagree			Strongly Agree		
1.	Planning family activities is difficult because we misunderstand each other.	1	2	3	4	5	M1.
2.	In times of crisis we can turn to each other for support.	1	2	3	4	5	M2.
3.	We cannot talk to each other about the sadness we feel.	1	2	3	4	5	M3.
4.	Individuals are accepted for who they are.	1	2	3	4	5	M4.
5.	We avoid discussing our fears and concerns.	1	2	3	4	5	M5.
6.	We can express feelings to each other.	1	2	3	4	5	M6.
7.	There are lots of bad feelings in the family.	1	2	3	4	5	M7.
8.	We feel accepted for who we are.	1	2	3	4	5	M8.
9.	Making decisions is a problem for our family.	1	2	3	4	5	M9.
10.	We are able to make decisions about how to solve problems.	1	2	3	4	5	M10.
11.	We don't get along well together.	1	2	3	4	5	M11.
12.	We confide in each other.	1	2	3	4	5	M12.

YOUR HEALTH AND MOOD SECTION

1. In general, would you say your health is: I1.
(1) ☐ Excellent (2) ☐ Very Good (3) ☐ Good (4) ☐ Fair (5) ☐ Poor
2. Have you **ever in your life** had two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun? I14.
(1) ☐ Yes (5) ☐ No (Skip to Question 3)
- 2a. If there was such a two-week period, did your work or relationships suffer? I14a.
(1) ☐ Yes (5) ☐ No
- 2b. If there was such a two-week period, did you get counseling or psychotherapy? I14b.
(1) ☐ Yes (5) ☐ No
- 2c. If there was such a two-week period, did you get medication for this condition? I14c.
(1) ☐ Yes (5) ☐ No
3. In the **past 6 months**, have you had two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun? I12.
(1) ☐ Yes (5) ☐ No (Skip to Question 4)
- 3a. If there was such a two-week period (**in the past 6 months**), did your work or relationships suffer? I12a.
(1) ☐ Yes (5) ☐ No
- 3b. If there was such a two-week period (**in the past 6 months**), did you get counseling or psychotherapy? I12b.
(1) ☐ Yes (5) ☐ No
- 3c. If there was such a two-week period, (**in the past 6 months**) did you get medication for this problem? I12c.
(1) ☐ Yes (5) ☐ No
4. Are you **currently** receiving counseling, psychotherapy, or medication for depression or emotional problems? I13.
(1) ☐ Yes (5) ☐ No

SYMPTOMS OF STRAIN SECTION

LISTED BELOW ARE SOME SYMPTOMS OF STRAIN THAT PEOPLE SOMETIMES HAVE. *Please Read Each One Carefully And Check The Answer Which Best Reflects How Much That Symptom Has Bothered You During the Past Three Months.*

		<u>1</u> <u>Not at all</u>	<u>2</u> <u>A little</u>	<u>3</u> <u>Quite a bit</u>	<u>4</u> <u>Extremely</u>	
1.	Suddenly scared for no reason	1	2	3	4	K1.
2.	Feeling fearful	1	2	3	4	K2.
3.	Faintness, dizziness, or weakness	1	2	3	4	K3.
4.	Nervousness or shakiness inside	1	2	3	4	K4.
5.	Heart pounding or racing	1	2	3	4	K5.
6.	Trembling	1	2	3	4	K6.
7.	Feeling tense or keyed up	1	2	3	4	K7.
8.	Headaches	1	2	3	4	K8.
9.	Spells of terror or panic	1	2	3	4	K9.
10.	Feeling restless, can't sit still	1	2	3	4	K10.
11.	Feeling low in energy--slowed down	1	2	3	4	K11.
12.	Blaming yourself for things	1	2	3	4	K12.
13.	Crying easily	1	2	3	4	K13.
14.	Loss of sexual interest or pleasure	1	2	3	4	K14.
15.	Poor appetite	1	2	3	4	K15.
16.	Difficulty falling asleep, staying asleep	1	2	3	4	K16.
17.	Feeling hopeless about the future	1	2	3	4	K17.
18.	Feeling blue	1	2	3	4	K18.
19.	Feeling lonely	1	2	3	4	K19.
20.	Feeling trapped or caught	1	2	3	4	K20.
21.	Worrying too much about things	1	2	3	4	K21.
22.	Feeling no interest in things	1	2	3	4	K22.
23.	Thoughts of ending your life	1	2	3	4	K23.
24.	Feeling everything is an effort	1	2	3	4	K24.
25.	Feelings of worthlessness	1	2	3	4	K25.

COPING SECTION

1. Imagine that you are afraid of the dentist and have to get some dental work done. Which of the following would you do? Please answer **yes** or **no** for each choice.

		YES	NO	
a.	I would ask the dentist exactly what s/he was going to do.	1	5	L1_1
b.	I would take a tranquilizer or have a drink before going.	1	5	L1_2
c.	I would try to think about pleasant memories.	1	5	L1_3
d.	I would want the dentist to tell me when I would feel pain.	1	5	L1_4
e.	I would try to sleep.	1	5	L1_5
f.	I would watch all the dentist's movements and listen for the sound of the drill.	1	5	L1_6
g.	I would watch the flow of water from my mouth to see if it contained blood.	1	5	L1_7
h.	I would do mental puzzles in my mind.	1	5	L1_8

2. Imagine that you are being held hostage by a group of armed terrorists in a public building. Which of the following would you do?

		YES	NO	
a.	I would sit by myself and have as many daydreams and fantasies as I could.	1	5	L2_1
b.	I would stay alert and try to keep myself from falling asleep.	1	5	L2_2
c.	I would exchange life stories with the other hostages.	1	5	L2_3
d.	If there was a radio present, I would stay near it and listen to the bulletins about what the police were doing.	1	5	L2_4
e.	I would watch every movement of my captors and keep an eye on their weapons.	1	5	L2_5
f.	I would try to sleep as much as possible.	1	5	L2_6
g.	I would think about how nice it's going to be when I get home.	1	5	L2_7
h.	I would make sure I knew where every possible exit was.	1	5	L2_8

3. Imagine that due to a large drop in sales, it is rumored that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about lay-off has been made and will be announced in several days. Please answer **yes** or **no** for each choice.

		YES	NO	
a.	I would talk to my fellow workers to see if they knew anything about what the supervisor's evaluation of me said.	1	5	L3_1
b.	I would review the list of duties for my present job and try to figure out if I had fulfilled them all.	1	5	L3_2
c.	I would go to the movies to take my mind off things.	1	5	L3_3
d.	I would try to remember any arguments or disagreements I might have had with the supervisor that would have lowered his opinion of me.	1	5	L3_4
e.	I would push all thoughts of being laid off out of my mind.	1	5	L3_5
f.	I would tell my spouse that I'd rather not discuss my chances of being laid off.	1	5	L3_6
g.	I would try to think which employees in my department the supervisor might have thought had done the worst job.	1	5	L3_7
h.	I would continue doing my work as if nothing special was happening.	1	5	L3_8

4. Imagine that you are on an airplane, 30 minutes from your destination, when the plane unexpectedly goes into a deep dive and then suddenly levels off. After a short time, the pilot announces that nothing is wrong, although the rest of the ride may be rough. You, however, are not convinced that all is well. Please answer **yes** or **no** for each choice.

		YES	NO	
a.	I would carefully read the information provided about safety features in the plane and make sure I knew where the emergency exits were.	1	5	L4_1
b.	I would make small talk with the passenger beside me.	1	5	L4_2
c.	I would watch the end of the movie, even if I had seen it before.	1	5	L4_3
d.	I would call for the flight attendant and ask her/him exactly what the problem was.	1	5	L4_4
e.	I would order a drink or tranquilizer from the stewardess.	1	5	L4_5
f.	I would listen carefully to the engines for unusual noises and would watch the crew to see if their behavior was out of the ordinary.	1	5	L4_6
g.	I would talk to the passenger beside me about what might be wrong.	1	5	L4_7
h.	I would settle down and read a book or magazine or write a letter.	1	5	L4_8

5. This set of questions deals with ways you've been coping with the stress in your life that goes with your wife/partner possibly having the altered BRCA1 gene associated with risk for breast cancer. Obviously, different people deal with this stress in different ways, but we are interested in how you've tried to deal with it. Each item says something about a particular way of coping. We want to know *to what extent* you've been doing what the item says, how *much* or how *frequently*. Don't answer on the basis of whether it seems to be working, but just whether or not you're doing it. Use these response choices below and try not to let one answer influence another. Make your answers as true FOR YOU as you can.

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>	
a.	I've been turning to work or other activities to take my mind off things.	1	2	3	4	L7_a.
b.	I've been concentrating my efforts on doing something about her situation.	1	2	3	4	L7_b.
c.	I've been saying to myself "this isn't possible."	1	2	3	4	L7_c.
d.	I've been using alcohol or other drugs to make myself feel better.	1	2	3	4	L7_d.
e.	I've been getting emotional support from others.	1	2	3	4	L7_e.
f.	I've been giving up trying to deal with it.	1	2	3	4	L7_f.
g.	I've been taking action to try to make the situation better.	1	2	3	4	L7_g.
h.	I've been refusing to believe that it is possible she has the gene.	1	2	3	4	L7_h.
i.	I've been saying things to let my unpleasant feelings escape.	1	2	3	4	L7_i.
j.	I've been using alcohol or other drugs to help me get through it.	1	2	3	4	L7_j.
k.	I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4	L7_k.
l.	I've been trying to come up with a strategy for what to do.	1	2	3	4	L7_l.

		<i>I haven't been doing this at all 1</i>	<i>I've been doing this a little bit 2</i>	<i>I've been doing this some 3</i>	<i>I've been doing this a lot 4</i>	
m.	I've been getting comfort and understanding from someone.	1	2	3	4	L7_m.
n.	I've been giving up the attempt to cope.	1	2	3	4	L7_n.
o.	I've been accepting the possibility that she might have the gene.	1	2	3	4	L7_o.
p.	I've been expressing my negative feelings.	1	2	3	4	L7_p.
q.	I've been trying to find comfort in my religion or spiritual beliefs.	1	2	3	4	L7_q.
r.	I've been learning to live with the possibility she might have the gene.	1	2	3	4	L7_r.
s.	I've been thinking hard about what steps to take.	1	2	3	4	L7_s.
t.	I've been praying or meditating.	1	2	3	4	L7_t.
u.	I've been making fun of the situation.	1	2	3	4	L7_u.
v.	I've been giving pep talks and encouraging my wife/partner.	1	2	3	4	L7_v.
w.	I've been denying or hiding my anger around my wife/partner.	1	2	3	4	L7_w.
x.	I've been denying or hiding my own worries around my wife/partner.	1	2	3	4	L7_x.
y.	I've been trying to give my wife/partner opportunities to talk about her worries.	1	2	3	4	L7_y.
z.	I've been trying to find out what my wife/partner is feeling.	1	2	3	4	L7_z.
aa.	I've been avoiding talking about my own problems around my wife/partner.	1	2	3	4	L7_aa.
bb.	I've acted more positive around my wife/partner than I feel.	1	2	3	4	L7_bb.

6. **At your worst**, how distressed did you feel about your wife/partner's diagnosis and treatment of cancer? **L8.**

7. During that time, did you ever have two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually like to do for fun?

(1) ☐ Yes (5) ☐ No (Skip to Question 8)

L9.

b. If there was such a two-week period, did you get counseling or psychotherapy? (1) ☐ Yes (5) ☐ No **L9b.**

8. For each of the statements on the following page, indicate the degree to which this change occurred in your life as a result of your wife/partner being diagnosed and treated for breast cancer.
Please use the following scale:

- ☐ Does not apply because I was not with my wife/partner when she was being treated for breast cancer. **L6.**

		<i>No Change</i>	<i>Very Small Degree</i>	<i>Small Degree</i>	<i>Moderate Degree</i>	<i>Great Degree</i>	<i>Very Great Degree</i>	
a.	My priorities about what is important in life.	1	2	3	4	5	6	L6_a.
b.	I'm more likely to try to change things which need changing.	1	2	3	4	5	6	L6_b.
c.	An appreciation for the value of my own life.	1	2	3	4	5	6	L6_c.
d.	A feeling of self-reliance.	1	2	3	4	5	6	L6_d.
e.	A better understanding of spiritual matters.	1	2	3	4	5	6	L6_e.
f.	Knowing that I can count on people in times of trouble.	1	2	3	4	5	6	L6_f.
g.	A sense of closeness with others.	1	2	3	4	5	6	L6_g.
h.	Knowing I can handle difficulties.	1	2	3	4	5	6	L6_h.
i.	A willingness to express my emotions.	1	2	3	4	5	6	L6_i.
j.	Being able to accept the way things work out.	1	2	3	4	5	6	L6_j.
k.	Appreciating each day.	1	2	3	4	5	6	L6_k.
l.	Having compassion for others.	1	2	3	4	5	6	L6_l.
m.	I'm able to do better things with my life.	1	2	3	4	5	6	L6_m.
n.	New opportunities are available which wouldn't have been otherwise.	1	2	3	4	5	6	L6_n.

9. During the time in which your wife/partner was being treated for breast cancer, how often did you do the following to help her manage the emotional distress?

☐ Does not apply because I was not with my wife/partner when
(-8) she was being treated for breast cancer.

		Never Very Often					
		1	2	3	4	5	
1.	Gave her advice?						L10a.
2.	Went out of your way not to upset her?						L10b.
3.	Agreed with her to avoid an argument?						L10c.
4.	Acted more optimistic than you felt?						L10d.
5.	Kept your own problems to yourself?						L10e.
6.	Made up after an argument more quickly than before?						L10f.
7.	Apologized even when you didn't feel you were wrong?						L10g.
8.	Told her to calm down or relax?						L10h.
9.	Hid information that may upset her?						L10i.
10.	Stayed out of her problems?						L10j.
11.	Let your own problems take a "back seat" to her needs?						L10k.
12.	Gave her space when she was upset?						L10l.

We thank you for all of your valued participation in this study.



WOMEN'S HEALTH STUDY
Partner Post-Results Questionnaire

Today's Date _____

ID# _____

Spouse/Partner Post-Results Questionnaire
(8 Month Follow-Up after Partner Received Results)

Genetic Testing

1. Did you go with your spouse/partner to get her test results?

P6

(1) ☐ Yes (5) ☐ No (-8) ☐ Not Applicable (she received results by mail or over the telephone)

2. To your understanding, what were the results of your spouse/partner's genetic testing?

P5

0 ☐ An altered gene was NOT FOUND for either BRCA1 or BRCA2

└─ Even though no alteration was found for BRCA1 or BRCA2, Do you believe there is a possibility that your spouse/partner has another altered gene conveying an increased risk for breast and ovarian cancer?

(1) ☐ Yes (5) ☐ No

N13

1 ☐ An altered gene was FOUND for either BRCA1 or BRCA2

3 ☐ I don't know the results

3. When your spouse/partner received her genetic test results, what were your reactions?

☐ Not Applicable -- I don't know my partner's results.

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>	
		1	2	3	4	5
a.	I felt wonderful.	1	2	3	4	5
b.	I felt depressed.	1	2	3	4	5
c.	I felt she had been told what she knew all along.	1	2	3	4	5
d.	I felt relieved about being more certain.	1	2	3	4	5
e.	I did not believe the results.	1	2	3	4	5
f.	I fell apart emotionally.	1	2	3	4	5
g.	I felt anxious.	1	2	3	4	5
h.	I felt angry.	1	2	3	4	5

B18c_a.

B18c_b.

B18c_c.

B18c_d.

B18c_e.

B18c_f.

B18c_g.

B18c_h.

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>	
i.	I felt prepared for the future.	1	2	3	4	5
j.	I felt worried about the future.	1	2	3	4	5
k.	I felt she had done all she needed to do.	1	2	3	4	5
l.	I did not feel very differently.	1	2	3	4	5
m.	[For those who have daughters]. I wanted my daughters to be tested as soon as possible.	1	2	3	4	5

B18c_i.

B18c_j.

B18c_k.

B18c_l.

B18c_m.

4. To what extent did you do the following after your spouse/partner got her genetic results?

		<i>Never</i>				<i>Very Often</i>
a.	Gave her advice?	1	2	3	4	5
b.	Went out of your way not to upset her?	1	2	3	4	5
c.	Agreed with her to avoid an argument?	1	2	3	4	5
d.	Acted more optimistic than you felt?	1	2	3	4	5
e.	Kept your own problems to yourself?	1	2	3	4	5
f.	Made up after an argument more quickly than before?	1	2	3	4	5
g.	Apologized even when you didn't feel you were wrong?	1	2	3	4	5
h.	Told her to calm down or relax?	1	2	3	4	5
i.	Hid information that may upset her?	1	2	3	4	5
j.	Stayed out of her problems?	1	2	3	4	5
k.	Let your own problems take a "back seat" to her needs?	1	2	3	4	5
l.	Gave her space when she was upset?	1	2	3	4	5

L10a

L10b

L10c

L10d

L10e

L10f

L10g

L10h

L10i

L10j

L10k

L10l

5. How distressed were you when you heard your spouse/partner's genetic test results?

Not At All Distressed					Very Distressed	Doesn't Apply <i>I don't know what her results are</i>
1	2	3	4	5		-8

6. In your opinion, how distressed was your spouse/partner when she received genetic test results?

Not At All Distressed				Very Distressed
1	2	3	4	5

7. Overall, do you regret your spouse/partner's decision to obtain her results?

Not At All				Very Much So
1	2	3	4	5

8. Do you think it is beneficial to have genetic testing for risk of breast and ovarian cancer available to women?

B55

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

For the next set of questions, we would like to ask about the impact your spouse/ partner's receiving results has had on different areas of your family's life.

9. On the whole, what effect has her testing had on your life?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect
1	2	3	4	5

N15

10. Think about your everyday family life. What effect would you say getting the genetic test results has had?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect
1	2	3	4	5

N16

11. What effect has your spouse/partner getting her results had on your work in and outside of the home?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect
1	2	3	4	5

N17

12. How has it affected your anxiety about the future?

Less Anxiety	No Change	More Anxiety
1	2	3

N18

13. What effect has your spouse/partner getting her results had on your concerns for your child's/children's future?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect	Not Applicable
1	2	3	4	5	-8

N19

14. Psychologists have developed a standardized scale for comparing stressful situations with 0 representing no stress and 100 representing the greatest stress. Using this scale, North American samples have given the following ratings to some stressful events:

Change in residence is assigned a stress score of 20

Pregnancy is 40

Death of a close family member is 63

Death of a spouse is 100

Keeping in mind the ratings listed above, Please use any number between 0-100 with 0 representing no stress and 100 representing the greatest stress:

- a. For only those whose partners have had breast or ovarian cancer, how would you rate your stress level when you heard your partner had been diagnosed?

Spouse/partner's diagnosis of Cancer _____

- b. Now, how would you rate your stress when you heard the results of your spouse/partner's genetic testing?

Stress of hearing partner's genetic results _____

N4

15. How often have you discussed genetic testing for breast and ovarian cancer with your spouse/partner?

B51

Never	Rarely	Sometimes	Often
1	2	3	4

15a. When you have these discussions, who generally initiates them?

B52

You	Your partner	Equally	Not Applicable
1	2	3	-8

15b. How satisfied are you with these discussions?

B53

Not At All	A Little	Somewhat	A Great Deal	Not Applicable
1	2	3	4	-8

16. How often does your spouse/partner express concern and seek support from you about the risk of breast and ovarian cancer to herself and women in her family?

Never	Rarely	Sometimes	Often
1	2	3	4

16a. How much of a burden is this on you?

B50

Not At All	A Little	Somewhat	A Great Deal	Not Applicable
1	2	3	4	-8

17. Overall, how much do you want your opinion to be taken into account in your partner's decisions **about what to do about her risk** for breast and ovarian cancer?

B58

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

18. Overall, what do you believe your spouse/partner's risk to be of developing breast or ovarian cancer (or developing breast or ovarian cancer again) **in the near future**?

B9b

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
0	1	2	3	4	5	6	7	8	9	10

19. Overall, what do you believe her risk to be of developing breast or ovarian cancer (or developing breast or ovarian cancer again) **at some point in her lifetime**? B10b

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
0	1	2	3	4	5	6	7	8	9	10

20. At the present time, do you feel you are adequately informed concerning your spouse/partner's risk for cancer and what can be done about it?

Not At All						Very Much	
1	2	3	4	5	6	7	

21. At the present time, do you feel you are adequately informed about the benefits and drawbacks of options available to women who have an altered BRCA1/BRCA2 gene? B46

Not At All						Very Much	
1	2	3	4	5	6	7	

22. How often do you worry about your partner/spouse developing breast/ovarian cancer (again)?

Not At All				All the Time	
1	2	3	4	5	

B27aa

23. To what extent do these worries interfere with your every day life?

Not At All				All the Time	
1	2	3	4	5	

B28a

24. How often do you worry about developing cancer yourself?

Not At All				All the Time	
1	2	3	4	5	

B31

Symptoms of Strain

LISTED BELOW ARE SOME SYMPTOMS OF STRAIN THAT PEOPLE SOMETIMES HAVE. *Please Read Each One Carefully And Circle The Answer Which Best Reflects How Much That Symptom Has Bothered You During the Past Three Months.*

		Not at all	A little	Quite a bit	Extremely	
1.	Suddenly scared for no reason	1	2	3	4	K1
2.	Feeling fearful	1	2	3	4	K2
3.	Faintness, dizziness, or weakness	1	2	3	4	K3
4.	Nervousness or shakiness inside	1	2	3	4	K4
5.	Heart pounding or racing	1	2	3	4	K5
6.	Trembling	1	2	3	4	K6
7.	Feeling tense or keyed up	1	2	3	4	K7
8.	Headaches	1	2	3	4	K8
9.	Spells of terror or panic	1	2	3	4	K9
10.	Feeling restless, can't sit still	1	2	3	4	K10
11.	Feeling low in energy--slowed down	1	2	3	4	K11
12.	Blaming yourself for things	1	2	3	4	K12
13.	Crying easily	1	2	3	4	K13
14.	Loss of sexual interest or pleasure	1	2	3	4	K14
15.	Poor appetite	1	2	3	4	K15
16.	Difficulty falling asleep, staying asleep	1	2	3	4	K16
17.	Feeling hopeless about the future	1	2	3	4	K17
19.	Feeling blue	1	2	3	4	K19
19.	Feeling lonely	1	2	3	4	K19
20.	Feeling trapped or caught	1	2	3	4	K20
21.	Worrying too much about things	1	2	3	4	K21
22.	Feeling no interest in things	1	2	3	4	K22
23.	Thoughts of ending your life	1	2	3	4	K23
24.	Feeling everything is an effort	1	2	3	4	K24
25.	Feelings of worthlessness	1	2	3	4	K25

26. To what extent are any of the above current symptoms a result of your partner getting genetic testing?

Not At All	A Little	Some	Quite a Bit	Very Much
1	2	3	4	5

K26

Your Views of Prevention and Treatment

1. To what extent do you agree or disagree with the following statements?

		Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Somewhat Agree	
a.	In the next year, there will be dramatic breakthroughs in the <u>prevention</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7a
b.	In the next year, there will be dramatic breakthroughs in the <u>treatment</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7b
c.	In the next year, the length of <u>survival</u> after diagnosis of breast cancer will increase.	1	2	3	4	5	N7c
d.	In the next year, the length of <u>survival</u> after diagnosis of ovarian cancer will increase.	1	2	3	4	5	N7d
e.	In the next 5 years, there will be dramatic breakthroughs in the <u>prevention</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7e
f.	In the next 5 years, there will be dramatic breakthroughs in the <u>treatment</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7f
g.	In the next five years, the length of <u>survival</u> after diagnosis of breast cancer will increase.	1	2	3	4	5	N7g
h.	In the next five years, the length of <u>survival</u> after diagnosis of ovarian cancer will increase.	1	2	3	4	5	N7h
i.	In the future, all women will routinely receive genetic testing for risk of breast and ovarian cancer.	1	2	3	4	5	N7i

We thank you for all of your valued participation in this study.

☐ ☐ ☐ ☐ - ☐ ☐ ☐



WOMEN'S HEALTH STUDY

Sister Questionnaire

SISTER QUESTIONNAIRE

HEALTH SECTION

1. Have you ever been diagnosed with Breast cancer? (1) ☐ Yes (5) ☐ No B1u.
2. Have you ever been diagnosed with Ovarian cancer? (1) ☐ Yes (5) ☐ No B5.

Please answer the following questions only if you have been diagnosed at any time with breast or ovarian cancer.

I have never been diagnosed with breast or ovarian cancer. ☐ Skip to 11

3. When were you first diagnosed with breast cancer? B1.
Month _____ Year _____ ☐ Not Applicable
4. When were you first diagnosed with ovarian cancer? B5a.
Month _____ Year _____ ☐ Not Applicable
5. Have you received any of the following treatments?
- | | | | |
|--------------|----------------------------------|---------------------------------|------|
| Chemotherapy | (1) <input type="checkbox"/> Yes | (5) <input type="checkbox"/> No | B4a. |
| Radiation | (1) <input type="checkbox"/> Yes | (5) <input type="checkbox"/> No | B4b. |
| Surgery | (1) <input type="checkbox"/> Yes | (5) <input type="checkbox"/> No | B4c. |
6. Have you ever had any of the following surgical procedures?
- 6a. **Lumpectomy** (Removal of lump from breast) B6a.
(1) ☐ Yes (5) ☐ No If yes, when? Month _____ Year _____ B6a2.
- 6b. **Unilateral mastectomy** (Removal of one breast) B6c.
(1) ☐ Yes (5) ☐ No If yes, when? Month _____ Year _____ B6c2.
- 6c. **Bilateral mastectomy** (Removal of both breasts) B6e.
(1) ☐ Yes (5) ☐ No If yes, when? Month _____ Year _____ B6e2.
- 6d. **Hysterectomy** (Removal of uterus) B6d.
(1) ☐ Yes (5) ☐ No If yes, when? Month _____ Year _____ B6d2.
- 6e. **Oophorectomy** (Removal of ovaries) B6b.
(1) ☐ Yes (5) ☐ No If yes, when? Month _____ Year _____ B6b2.

15. In general, would you say your health is:

I1.

☐ Excellent
(1)

☐ Very Good
(2)

☐ Good
(3)

☐ Fair
(4)

☐ Poor
(5)

16. Compared to one year ago, how would you rate your health in general now?
(Please Check one only)

I2.

- (1) ☐ Much better now than one year ago
- (2) ☐ Somewhat better now than one year ago
- (3) ☐ About the same as one year ago
- (4) ☐ Somewhat worse now than one year ago
- (5) ☐ Much worse than one year ago

FAMILY HISTORY SECTION

In the next set of questions, we are interested in learning about your family's experience with breast cancer.

1. Have any of your relatives been diagnosed with breast cancer?

B91.

- (1) ☐ Yes (2) ☐ No (3) ☐ I Don't Know

2. If Yes, how many of the following relatives been affected by (diagnosed with) breast cancer? (How many relatives for each category where applicable?)

	<u>Relative:</u>	<u>How Many?</u>
a.	Sister(s)	
b.	Mother	
c.	Grandmother(s) Maternal	
d.	Grandmother(s) Paternal	
e.	Aunt(s) Maternal	
f.	Aunt(s) Paternal	
g.	Cousin(s) Maternal	
h.	Cousin(s) Paternal	
i.	Wife	
j.	Daughter(s)	

B92a.

B92b.

B92c1.

B92c2.

B92d1.

B92d2.

B92e1.

B92e2.

B92f.

B92g.

8. How often do you discuss your family's risk for breast cancer with **your sister who gave us your name**?

B75.

Never	Rarely	Sometimes	Often
1	2	3	4

- 8a. If you have these discussions, who generally initiates them?

B75a.

You	Your Sister	Equally	No discussions
1	2	3	4

- 8b. How satisfied are you with these discussions?

B75b.

Not At All	A Little	Somewhat	A Great Deal	No discussions
1	2	3	4	5

9. How often does **your sister** seek your support concerning the risk of breast cancer to women in your family?

B49a.

Never	Rarely	Sometimes	Often
1	2	3	4

10. How much of a **burden** is this on you?

B50.

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

GENETIC TESTING SECTION

Now, we have some questions about breast cancer diagnosis, treatment, and genetic testing.

1. We would like to know how much you have been informed about breast cancer. To what extent do you agree with the following statements?

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>		<i>I Don't Know</i>
a.	Mammography is effective in the early detection of breast cancer in women.	1	2	3	4	5	9

B20a.

4. Compared to how often you now talk to the women in your family about **genetic testing for breast cancer**, how much would you prefer to talk to them about this topic? **B96.**

A Lot Less	A Little Less	Same Amount	A Little More	A Lot More
1	2	3	4	5

5. Do you wish you had more information about genetic testing? **B98.**
- (1) ☐ Yes (5) ☐ No (3) ☐ No Opinion

6. How often do you discuss genetic testing for breast cancer with **your** sister (who gave us your name)? **B51a.**

Never	Rarely	Sometimes	Often
1	2	3	4

- 6a. If you have these discussions, who generally initiates them? **B52a.**

You	Your Sister	Equally	No discussions
1	2	3	4

- 6b. How satisfied are you with these discussions? **B53.**

Not At All	A Little	Somewhat	A Great Deal	No discussions
1	2	3	4	5

7. What are **your** plans concerning this genetic test at the present time? **B15c.**
(Please check one response).

- (1) _____ I will definitely take the test soon.
- (2) _____ I will definitely take the test, but I am not sure when.
- (3) _____ I will probably take the test.
- (4) _____ I am undecided whether I will take the test.
- (5) _____ I will probably not take the test.
- (6) _____ I will definitely not take the test.

11. Overall, how important are the opinions of the following family members in your decision whether to be tested for an altered gene associated with increased risk for breast cancer? (Circle *Not Applicable* if you do not have any relatives in that category.)

		Not At All	A Little	Some-what	A Great Deal	Not Applicable
a.	Sister(s)'s opinion matters	1	2	3	4	9
b.	Spouse/Partner's opinion matters	1	2	3	4	9
c.	Mother's opinion matters	1	2	3	4	9
d.	Daughter's opinion matters	1	2	3	4	9
e.	Other family member(s)'s opinions matter	1	2	3	4	9

B78a.

B78b.

B78c.

B78d.

B78e.

12. How pressured do you feel from the following family members to get tested for an altered gene? (Circle *Not Applicable* if you do not have any relatives in that category.)

		Not At All	A Little	Some-what	A Great Deal	Not Applicable
a.	Sister(s)	1	2	3	4	9
b.	Spouse/Partner	1	2	3	4	9
c.	Mother	1	2	3	4	9
d.	Daughter	1	2	3	4	9
e.	Other family member(s)	1	2	3	4	9

B79a.

B79b.

B79c.

B79d.

B79e.

13. How much of a **burden** is it on you when the women in your family pressure you to get tested for an altered gene?

B80.

No Burden	A Little Burden	Some Burden	A Great Burden	Not applicable, No Pressure
1	2	3	4	5

14. How distressed would you be if you took the test and found that you **did not** have an altered gene which conveys increased risk of breast cancer?

B70a.

Not At All Distressed		Very Distressed		
1	2	3	4	5

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>	
h.	I would feel anxious.	1	2	3	4	5
i.	I would feel angry.	1	2	3	4	5
j.	I would not feel very differently.	1	2	3	4	5

B82h.

B82i.

B82j.

		<i>Not At All</i>			<i>All The Time</i>	
18.	How often do you worry about having an altered gene associated with risk for breast cancer among women?	1	2	3	4	5
19.	To what extent do any worries you have about this genetic alteration interfere with every day life?	1	2	3	4	5
20.	How often do you worry about women in your family developing breast cancer?	1	2	3	4	5
21.	How often do you worry about developing cancer yourself?	1	2	3	4	5
22.	How much do worries about developing cancer interfere with your everyday life?	1	2	3	4	5

B83.

B84.

B85.

B86.

B87.

23. How likely do you think it is that you have an altered gene which conveys increased risk for breast cancer in women relatives? (Please circle one)

B88.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
0	1	2	3	4	5	6	7	8	9	10

24. How much would it affect your health in the future if you had an altered gene which conveys increased risk for breast cancer in women relatives?

B89.

☐ Not at All ☐ A Little ☐ Somewhat ☐ A Great Deal ☐ I Don't Know
 (1) (2) (3) (4) (5)

25. Overall, what do you think your risk is of developing cancer (or developing cancer again) in the future?

B90.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
0	1	2	3	4	5	6	7	8	9	10

FAMILY RELATIONSHIPS SECTION

1. Please indicate the extent to which each of the following items currently describes **the family in which you grew up.**

		<i>Strongly Disagree</i>		<i>Strongly Agree</i>			
		1	2	3	4	5	
a.	Planning family activities is difficult because we misunderstand each other.	1	2	3	4	5	M1.
b.	In times of crisis we can turn to each other for support.	1	2	3	4	5	M2.
c.	We cannot talk to each other about the sadness we feel.	1	2	3	4	5	M3.
d.	Individuals are accepted for who they are.	1	2	3	4	5	M4.
e.	We avoid discussing our fears and concerns.	1	2	3	4	5	M5.
f.	We can express feelings to each other.	1	2	3	4	5	M6.
g.	There are lots of bad feelings in the family.	1	2	3	4	5	M7.
h.	We feel accepted for who we are.	1	2	3	4	5	M8.
i.	Making decisions is a problem for our family.	1	2	3	4	5	M9.
j.	We are able to make decisions about how to solve problems.	1	2	3	4	5	M10.
k.	We don't get along well together.	1	2	3	4	5	M11.
l.	We confide in each other.	1	2	3	4	5	M12.

2. Is there anyone in your life with whom you can share your most private feelings without holding back? C21.

☐ Yes ☐ No

- 2a. Do you have that kind of relationship with **your sister** (who gave us your name)? C21c.

☐ Yes ☐ No

3. How often do you talk to **your sister**? (check one) C22.

☐ Most every day
☐ A few times a week
☐ A few times a month
☐ Once a month
☐ Less than once a month
☐ Less than once a year
☐ Never

8. Are you currently working for pay outside the home? A7.
 (1) ☐ Yes (5) ☐ No
9. If yes, about how many hours per week are you working for pay? A8.
 Less than 10 10-20 21-30 31-40 41 or more
☐ (1) ☐ (2) ☐ (3) ☐ (4) ☐ (5)
10. What is the highest level of education you have completed? (Check one) A9.
- | | |
|---|--|
| 1 <input type="checkbox"/> Less than 9th grade | 5 <input type="checkbox"/> Completed college |
| 2 <input type="checkbox"/> Dropped out of high school | 6 <input type="checkbox"/> Some graduate or professional training |
| 3 <input type="checkbox"/> Completed high school | 7 <input type="checkbox"/> Completed graduate or professional training |
| 4 <input type="checkbox"/> Some college | |

The following two questions are optional, but we hope that you will provide this information.

11. What is your household's total income? (Check one) A10.
- | | | |
|---|---|--|
| (1) <input type="checkbox"/> Less than \$10,000 | (4) <input type="checkbox"/> \$30,000 to \$39,999 | (7) <input type="checkbox"/> \$60,000 to \$69,999 |
| (2) <input type="checkbox"/> \$10,000 to \$19,999 | (5) <input type="checkbox"/> \$40,000 to \$49,999 | (8) <input type="checkbox"/> Greater than \$69,999 |
| (3) <input type="checkbox"/> \$20,000 to \$29,999 | (6) <input type="checkbox"/> \$50,000 to \$59,999 | |
12. How many people (adults and children) does this income support? _____ A11.
-

THANK YOU VERY MUCH
FOR YOUR PARTICIPATION.

				-			
--	--	--	--	---	--	--	--

WOMEN'S HEALTH STUDY
Sister Post-Results Questionnaire

SISTER POST-RESULTS QUESTIONNAIRE
(For Sisters of Women who received genetic testing results 8 months prior)

Throughout this questionnaire, items referring to "sister" are asking about your sister who gave us your name.

1. Did your sister (who gave us your name) tell you her genetic test results?
(1) ☐ Yes (5) ☐ No

2. What is your understanding of your sister's genetic testing results?

P5a

0 ☐ An altered gene was NOT FOUND for either BRCA1 or BRCA2

→ Even though no alteration was found for BRCA1 or BRCA2, Do you believe there is a possibility that your sister has another altered gene conveying an increased risk for breast and ovarian cancer?

(1) ☐ Yes (5) ☐ No

N13b

1 ☐ An altered gene was FOUND for either BRCA1 or BRCA2

3 ☐ I don't know the results

3. Do **you** plan to get genetic testing for breast and ovarian cancer (BRCA1 OR BRCA2)?

P1

(1) ☐ Yes

(5) ☐ No

(3) ☐ Undecided

(4) ☐ I have Already Received Genetic Test Results myself for breast and ovarian cancer.

4. To what extent did you do the following after your sister got her genetic results?

		Never					Very Often
		1	2	3	4	5	
a.	Gave her advice?	1	2	3	4	5	L10a
b.	Went out of your way not to upset her?	1	2	3	4	5	L10b
c.	Agreed with her to avoid an argument?	1	2	3	4	5	L10c
d.	Acted more optimistic than you felt?	1	2	3	4	5	L10d
e.	Kept your own problems to yourself?	1	2	3	4	5	L10e
f.	Made up after an argument more quickly than before?	1	2	3	4	5	L10f
g.	Apologized even when you didn't feel you were wrong?	1	2	3	4	5	L10g

		Never Very Often				
		1	2	3	4	5
h.	Told her to calm down or relax?	1	2	3	4	5
i.	Hid information that may upset her?	1	2	3	4	5
j.	Stayed out of her problems?	1	2	3	4	5
k.	Let your own problems take a "back seat" to her needs?	1	2	3	4	5
l.	Gave her space when she was upset?	1	2	3	4	5

L10h

L10i

L10j

L10k

L10l

5. After hearing your sister's results, are you now considering any of the following options? Please **circle** only one response for each option.

		Done Before Sister Obtained Results	Definitely Will NOT Do	Probably Will NOT Do	Probably Will Do	Definitely Will Do	Done After Sister Obtained Results	Does Not Apply to Me
a.	Prophylactic Oophorectomy (removal of ovaries)	0	1	2	3	4	5	-8
b.	Prophylactic Mastectomy	0	1	2	3	4	5	-8
c.	Monthly Breast Self-Exams	0	1	2	3	4	5	-8
d.	Yearly Physical Exams	0	1	2	3	4	5	-8
e.	Mammograms at least once a year	0	1	2	3	4	5	-8
f.	Change Diet	0	1	2	3	4	5	-8
g.	Begin Homeopathic medicines/remedies	0	1	2	3	4	5	-8
h.	Attend to spiritual issues	0	1	2	3	4	5	-8
i.	Encourage/instruct Children to maintain surveillance	0	1	2	3	4	5	-8
j.	Encourage my relatives to be tested	0	1	2	3	4	5	-8
k.	Discourage my relatives from being tested	0	1	2	3	4	5	-8

B103a

B103b

B103c

B103d

B103e

B103j

B103k

B103l

B103m

B103f

B103g

6. How distressed were you by your sister's genetic test results?

P2

Not At All Distressed					Very Distressed	Doesn't Apply I don't know what her results are
1	2	3	4	5		-8

7. In your opinion, how distressed was your sister when she received genetic test results?

P3

Not At All Distressed				Very Distressed
1	2	3	4	5

8. Overall, do you regret your sister's decision to obtain her results?

B71c

Not At All				Very Much So
1	2	3	4	5

9. Psychologists have developed a standardized scale for comparing stressful situations with 0 representing no stress and 100 representing the greatest stress. Using this scale, North American samples have given the following ratings to some stressful events:

Change in residence is assigned a stress score of 20

Pregnancy is 40

Death of a close family member is 63

Death of a spouse is 100

Keeping in mind the ratings listed above, Please use any number between 0-100 with 0 representing no stress and 100 representing greatest stress:

- 9a. How would you rate the stress of being a member of a family at increased risk of breast and ovarian cancer?

N2

Being a member of a high risk family _____ (0-100)

- 9b. For only those of you who have had breast or ovarian cancer, how would you rate your stress level of being diagnosed?

Your diagnosis of cancer _____ (0-100)

N3c

- 9c. For only those whose sister has had breast or ovarian cancer, how would you rate your stress level of her being diagnosed?

Sister's diagnosis of cancer _____ (0-100)

N3d

- 9d. Now, how would you rate your stress when you heard the results of your sister's genetic testing?

Stress of hearing sister's genetic results _____ (0-100)

N4

10. In general, how often have you discussed genetic testing for breast and ovarian cancer with your sister?

P4

Never	Rarely	Sometimes	Often
1	2	3	4

- 10a. When you have these discussions, who generally initiates them?

P4a

You	Your Sister	Equally	Not Applicable
1	2	3	-8

- 10b. How satisfied are you with these discussions?

P4b

Not At All	A Little	Somewhat	A Great Deal	Not Applicable
1	2	3	4	-8

11. On the whole, what effect has your sister getting results had on your life?

Very Negative Effect	Somewhat Negative Effect	No Effect	Somewhat Positive Effect	Very Positive Effect
1	2	3	4	5

N15

12. How has your sister getting results affected your anxiety about the future?

Less Anxiety	No Change	More Anxiety
1	2	3

N18

13. In general, how much has your sister getting genetic results changed your life?

Not At All	A Little	Some	Quite a Bit	Very Much
1	2	3	4	5

N23

14. Do you think it is beneficial to have genetic testing for risk of breast and ovarian cancer available to women?

B55

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

15. How confident are you that **you** are coping effectively with the results of your sister's genetic testing?

Not At All Confident							Very Confident
1	2	3	4	5	6	7	

B48g

16. How confident are you that **your family members** are coping effectively with the results of your sister's genetic testing?

Not At All Confident							Very Confident
1	2	3	4	5	6	7	

B48h

17. How often do you talk with your sister?

N28s

Not at All	Rarely	Sometimes	Often	A Lot
1	2	3	4	5

18. How often do you talk with her when something important and/or difficult happens in your life?

N29s

Not at All	Rarely	Sometimes	Often	A Lot
1	2	3	4	5

19. Before she actually got her results, how often did you discuss getting genetic testing for breast and ovarian cancer with her?

N30s

Not at All	Rarely	Sometimes	Often	A Lot
1	2	3	4	5

20. In the last six months since your sister received her genetic test results, how often have you discussed the results with her?

N31s

Not at All	Rarely	Sometimes	Often	A Lot
1	2	3	4	5

21. Overall, to what extent do your family members talk about themselves as being a family at high risk for breast or ovarian cancer?

N32

Not at All	Rarely	Sometimes	Often	A Lot
1	2	3	4	5

22. When you catch-up on what's going on in your family, to what extent are people's experiences with breast or ovarian cancer a topic of conversation?

N33

Not at All	Rarely	Sometimes	Often	A Lot
1	2	3	4	5

23. In your family, to what extent do you agree on how to manage risk for breast or ovarian cancer? N34

Not at All	Rarely	Sometimes	Often	A Lot
1	2	3	4	5

24. Have there been any disagreements about managing risk for cancer in your family? N34a
- (1) ☐ Yes (5) ☐ No

25. Now, we would like to ask you some questions about worries you may or may not experience.

		Not At All					All The Time
a.	How often do you worry about developing breast cancer (OR developing breast cancer again)?	1	2	3	4	5	B27
b.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B28
c.	How often do you worry about developing ovarian cancer (OR developing ovarian cancer again)?	1	2	3	4	5	B110
d.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B111
e.	How often do you worry about your sister developing breast or ovarian cancer (OR developing breast or ovarian cancer again)?	1	2	3	4	5	B106a
f.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B107a
g.	How often do you worry about your other relatives having an altered gene associated with risk for breast and ovarian cancer?	1	2	3	4	5	B108a
h.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B109a

26. How often does your sister express concern and seek support from you about the risk of breast and ovarian cancer to herself and women in her family? B49b

Never	Rarely	Sometimes	Often
1	2	3	4

27. How much of a burden is this on you? B50

Not At All	A Little	Somewhat	A Great Deal	Not Applicable
1	2	3	4	-8

28. Overall, how much do you want your opinion to be taken into account in your sister's decisions about what to do about her risk for breast and ovarian cancer?

B58a

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

Your Health

I know we have asked these two questions before, but we would like to update our records.

1. Have you ever been diagnosed with Breast cancer? (1) ☐ Yes (5) ☐ No

B1u

1a. How long ago was that? _____
(years) (months)

2. Have you ever been diagnosed with Ovarian cancer? (1) ☐ Yes (5) ☐ No

B5

2a. How long ago was that? _____
(years) (months)

3. How often do you usually get a mammogram?

B32a

- 1 ☐ Never (I have never had a mammogram).
2 ☐ Less than Once a Year
3 ☐ Once a Year
4 ☐ More than Once a Year
-8 ☐ Does Not Apply because of surgery

4. How often do you perform self-examination of your breasts?

B33a

- 1 ☐ Never or rarely
2 ☐ Less than Once a Month
3 ☐ Monthly
4 ☐ More than Once a Month
-8 ☐ Does Not Apply because of surgery

5. How often do you get CA-125 screening for ovarian cancer?

B33b

- 1 ☐ Never (I have never had a CA-125 screening).
2 ☐ Less than Once a Year
3 ☐ Once a Year
4 ☐ More than Once a Year
-8 ☐ Does Not Apply because of surgery

6. How often do you get ultrasound screening for ovarian cancer?

B33c

- 1 ☐ Never (I have never had an ovarian ultrasound for cancer screening).
2 ☐ Less than Once a Year
3 ☐ Once a Year
4 ☐ More than Once a Year
-8 ☐ Does Not Apply because of surgery

Symptoms of Strain Section

LISTED BELOW ARE SOME SYMPTOMS OF STRAIN THAT PEOPLE SOMETIMES HAVE. *Please Read Each One Carefully And Circle The Answer Which Best Reflects How Much That Symptom Has Bothered You During the Past Three Months.*

		Not at all	A little	Quite a bit	Extremely	
1.	Suddenly scared for no reason	1	2	3	4	K1
2.	Feeling fearful	1	2	3	4	K2
3.	Faintness, dizziness, or weakness	1	2	3	4	K3
4.	Nervousness or shakiness inside	1	2	3	4	K4
5.	Heart pounding or racing	1	2	3	4	K5
6.	Trembling	1	2	3	4	K6
7.	Feeling tense or keyed up	1	2	3	4	K7
8.	Headaches	1	2	3	4	K8
9.	Spells of terror or panic	1	2	3	4	K9
10.	Feeling restless, can't sit still	1	2	3	4	K10
11.	Feeling low in energy--slowed down	1	2	3	4	K11
12.	Blaming yourself for things	1	2	3	4	K12
13.	Crying easily	1	2	3	4	K13
14.	Loss of sexual interest or pleasure	1	2	3	4	K14
15.	Poor appetite	1	2	3	4	K15
16.	Difficulty falling asleep, staying asleep	1	2	3	4	K16
17.	Feeling hopeless about the future	1	2	3	4	K17
19.	Feeling blue	1	2	3	4	K19
19.	Feeling lonely	1	2	3	4	K19
20.	Feeling trapped or caught	1	2	3	4	K20
21.	Worrying too much about things	1	2	3	4	K21
22.	Feeling no interest in things	1	2	3	4	K22
23.	Thoughts of ending your life	1	2	3	4	K23
24.	Feeling everything is an effort	1	2	3	4	K24
25.	Feelings of worthlessness	1	2	3	4	K25

K26. To what extent are these current symptoms a result of getting genetic testing?

Not At All	A Little	Some	Quite a Bit	Very Much
1	2	3	4	5

K26

Prevention and Treatment

To what extent do you agree with the following statements?

		Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree	
1.	In the next year, there will be dramatic breakthroughs in the <u>prevention</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7a
2.	In the next year, there will be dramatic breakthroughs in the <u>treatment</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7b
3.	In the next year, the length of <u>survival</u> after diagnosis of breast cancer will increase.	1	2	3	4	5	N7c
4.	In the next year, the length of <u>survival</u> after diagnosis of ovarian cancer will increase.	1	2	3	4	5	N7d
5.	In the next 5 years, there will be dramatic breakthroughs in the <u>prevention</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7e
6.	In the next 5 years, there will be dramatic breakthroughs in the <u>treatment</u> of breast and/or ovarian cancer.	1	2	3	4	5	N7f
7.	In the next five years, the length of <u>survival</u> after diagnosis of breast cancer will increase.	1	2	3	4	5	N7g
8.	In the next five years, the length of <u>survival</u> after diagnosis of ovarian cancer will increase.	1	2	3	4	5	N7h
9.	In the future, all women will routinely receive genetic testing for risk of breast and ovarian cancer.	1	2	3	4	5	N7i

Thank You Very Much for Your Participation!

☐ ☐ ☐ - ☐ ☐ ☐



LONG TERM FOLLOW-UP STUDY

Questionnaire

TODAY'S DATE _____

ID _____

LONGITUDINAL ASSESSMENT--for Men

This is a follow up questionnaire from a joint project being conducted by the University of Michigan Medical Center and the University of Pennsylvania Cancer Center. It is for people who have received results of genetic testing for an altered gene associated with risk of breast and ovarian cancer. As genetic testing becomes more routine, it is important for us to know how this information affects people's quality of life and future health care decisions. Thank you very much for your participation!

Genetic Testing Section

1. When did you receive your results of genetic testing? **B101.**
(Month/Year) _____
2. Did you encourage your relatives to be tested for BRCA1/BRCA2 before you obtained your results? **B102h.**
(1) ☐ Yes (5) ☐ No
3. Did you discourage your relatives from being tested for BRCA1/BRCA2 before you obtained your results? **B102i.**
(1) ☐ Yes (5) ☐ No
4. Please rate the extent to which each of the following were your reasons for getting your results.

		<div style="display: flex; justify-content: space-between; width: 100%;"> <i>Not at all</i> <i>Very Much So</i> </div>					
a.	To plan for the future.	1	2	3	4	5	B16b1.
b.	To reduce the uncertainty.	1	2	3	4	5	B16b2.
c.	To make decisions about family planning.	1	2	3	4	5	B16b5.
d.	To find out the risk that may be transmitted to my children.	1	2	3	4	5	B16b6.
e.	Family members wanted me to get testing.	1	2	3	4	5	B16b7.
f.	Other (describe) _____	1	2	3	4	5	B16b8.

5. Before getting your test results, how distressing had it been for you to know that your family may be at increased risk for breast cancer because of your family history?

Not At All Distressing				Very Distressing
1	2	3	4	5

B66b.

6. How distressed **did you expect to be** when you were told you have an altered BRCA1/BRCA2 gene (before you received results)?

Not At All Distressed				Very Distressed
1	2	3	4	5

B68b.

7. How distressed were you when you were told that you had an altered BRCA1 (or BRCA2) gene?

Not At All Distressed				Very Distressed
1	2	3	4	5

B69b.

8. Overall, do you regret the decision to obtain your results?

Not At All				Very Much So
1	2	3	4	5

B71a.

9. When you received your results, what were your immediate reactions?

		Not At All			Very Much So	
		1	2	3	4	5
a.	I felt relieved about being more certain.	1	2	3	4	5
b.	I felt I had been told what I knew all along.	1	2	3	4	5
c.	I did not believe the results.	1	2	3	4	5
d.	I felt guilty.	1	2	3	4	5
e.	I was depressed.	1	2	3	4	5
f.	I worried about the future.	1	2	3	4	5

B82a.

B82b.

B82c.

B82d.

B82e.

B82f.

		Not At All					Very Much So	
		1	2	3	4	5		
g.	I thought I would just fall apart emotionally.	1	2	3	4	5		
h.	I felt anxious.	1	2	3	4	5		
i.	I felt angry.	1	2	3	4	5		

B82g.

B82h.

B82i.

10. We are interested in things that people do after being notified of their test results. After obtaining your results, which options are you now considering? Please circle one response.

		Definitely Will NOT Do	Probably Will NOT Do	Probably Will Do	Definitely Will Do	Done After Obtaining Results	Does Not Apply to Me
a.	Encouraging my relatives to be tested	1	2	3	4	5	-9
b.	Discouraging my relatives from being tested	1	2	3	4	5	-9
c.	Telling some of my relatives what my results were	1	2	3	4	5	-9
d.	Not telling some of my relatives what my results were	1	2	3	4	5	-9

B103f.

B103g.

B103h.

B103i.

11. Do you feel you were adequately informed about the benefits and drawbacks of genetic testing for risk of breast cancer **before getting your results?**

Not At All						Very Much	
1	2	3	4	5	6	7	

B44a.

12. Do you feel you are adequately informed about what it would mean for your children that you have an altered BRCA1/BRCA2 gene?

Not At All						Very Much	
1	2	3	4	5	6	7	

B47a.

13. How confident are you that **you** will cope effectively with the finding that you have an altered BRCA1/BRCA2 gene?

Not At All						Very Much
1	2	3	4	5	6	7

B48e.

14. How confident are you that **your family members** will cope effectively with the finding that you have an altered BRCA1/BRCA2 gene?

Not At All						Very Much
1	2	3	4	5	6	7

B48f.

15. How much have you discussed results of your genetic testing with female relatives **other than** your spouse/partner?

B105a.

Not at All	Very Little	Some	A Lot
1	2	3	4

16. When you have these discussions, who generally initiates them?

B105b.

You	Your Relatives	Equally
1	2	3

17. How satisfied are you with these discussions?

B105c.

Not At All	A Little	Somewhat	A Great Deal
1	2	3	4

Personal Attitudes Section

1. For each of these statements, please indicate the extent to which you agree or disagree by circling the appropriate number. There are no right or wrong answers. We are only interested in your opinions.

		<i>Strongly Disagree</i>			<i>Strongly Agree</i>		
a.	If you don't have your health, you don't have anything.	1	2	3	4	5	L5a.
b.	There are many things I care about more than my health.	1	2	3	4	5	L5b.
c.	Good health is of only minor importance in a happy life.	1	2	3	4	5	L5c.
d.	There is nothing more important than good health.	1	2	3	4	5	L5d.
e.	In uncertain times, I usually expect the best.	1	2	3	4	5	E1.
f.	It's easy for me to relax.	1	2	3	4	5	E2.
g.	If something can go wrong for me, it will.	1	2	3	4	5	E3.
h.	I always look on the bright side of things.	1	2	3	4	5	E4.
i.	I'm always optimistic about my future.	1	2	3	4	5	E5.
j.	I enjoy my friends a lot.	1	2	3	4	5	E6.
k.	It's important for me to keep busy.	1	2	3	4	5	E7.
l.	I hardly ever expect things to go my way.	1	2	3	4	5	E8.
m.	Things never work out the way I want them to.	1	2	3	4	5	E9.
n.	I don't get upset too easily.	1	2	3	4	5	E10.
o.	I'm a believer in the idea that "every cloud has a silver lining."	1	2	3	4	5	E11.
p.	I rarely count on good things happening to me.	1	2	3	4	5	E12.

2. Now, we would like to ask you some questions about your concerns of breast cancer in your family?

		<i>Not At All</i>		<i>All The Time</i>			
C1.	How often do you worry about your relatives developing breast cancer?	1	2	3	4	5	B32.
C2.	To what extent do these worries interfere with your every day life?	1	2	3	4	5	B33.
C3.	How often do you worry about your relatives having an altered gene associated with risk for breast cancer?	1	2	3	4	5	B34.
C4.	To what extent do these worries about interfere with your every day life?	1	2	3	4	5	B35.

Coping Section

1. Sometimes people can find unexpected benefits in difficulties. We are interested in the ways in which you might have made positive use of your knowing that you have an altered gene which increases the risk of breast cancer. For each of the statements below, indicate the degree to which your life has been affected positively by your finding you have an altered gene.

		<i>Not At All</i>	<i>A Very Small Degree</i>	<i>A Small Degree</i>	<i>A Moderate Degree</i>	<i>A Great Degree</i>	<i>A Very Great Degree</i>	
a.	My priorities about what is important in life.	1	2	3	4	5	6	L6a.
b.	I'm more likely to try to change things which need changing.	1	2	3	4	5	6	L6b.
c.	An appreciation for the value of my own life.	1	2	3	4	5	6	L6c.
d.	A feeling of self-reliance.	1	2	3	4	5	6	L6d.
e.	A better understanding of spiritual matters.	1	2	3	4	5	6	L6e.
f.	Knowing that I can count on people in times of troubles.	1	2	3	4	5	6	L6f.
g.	A sense of closeness with others.	1	2	3	4	5	6	L6g.
h.	Knowing I can handle difficulties.	1	2	3	4	5	6	L6h.
i.	A willingness to express my emotions.	1	2	3	4	5	6	L6i.

		<i>Not At All</i>	<i>A Very Small Degree</i>	<i>A Small Degree</i>	<i>A Moderate Degree</i>	<i>A Great Degree</i>	<i>A Very Great Degree</i>	
j.	Being able to accept the way things work out.	1	2	3	4	5	6	L6j.
k.	Appreciating each day.	1	2	3	4	5	6	L6k.
l.	Having compassion for others.	1	2	3	4	5	6	L6l.
m.	I'm able to do better things with my life.	1	2	3	4	5	6	L6m.
n.	New opportunities are available which wouldn't have been otherwise.	1	2	3	4	5	6	L6n.

2. This set of questions deals with ways you've been coping with the stress in your life that goes with knowing you have an altered gene associated with increased risk for breast cancer. Obviously, different people deal with things in different ways, but we are interested in how you've tried to deal with it. Each item says something about a particular way of coping. We want to know *to what extent* you've been doing what the item says, how *much* or how *frequently*. Don't answer on the basis of whether it seems to be working, but just whether or not you're doing it. Use these response choices below and try not to let one answer influence another. Make your answers as true FOR YOU as you can.

		<i>I haven't been doing this at all</i>	<i>I've been doing this a little bit</i>	<i>I've been doing this some</i>	<i>I've been doing this a lot</i>	
a.	I've been turning to work or other activities to take my mind off things.	1	2	3	4	L7a.
b.	I've been concentrating my efforts on doing something about my situation.	1	2	3	4	L7b.
c.	I've been saying to myself "this isn't possible."	1	2	3	4	L7c.
d.	I've been using alcohol or other drugs to make myself feel better.	1	2	3	4	L7d.
e.	I've been getting emotional support from others.	1	2	3	4	L7e.
f.	I've been giving up trying to deal with it.	1	2	3	4	L7f.
g.	I've been taking action to try to make the situation better.	1	2	3	4	L7g.
h.	I've been refusing to believe that it is possible that I have an altered gene.	1	2	3	4	L7h.

		<i>I haven't been doing this at all</i>	<i>I've been doing this a little bit</i>	<i>I've been doing this some</i>	<i>I've been doing this a lot</i>	
i.	I've been saying things to let my unpleasant feelings escape.	1	2	3	4	L7i.
j.	I've been using alcohol or other drugs to help me get through it.	1	2	3	4	L7j.
k.	I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4	L7k.
l.	I've been trying to come up with a strategy about what to do.	1	2	3	4	L7l.
m.	I've been getting comfort and understanding from someone.	1	2	3	4	L7m.
n.	I've been giving up the attempt to cope.	1	2	3	4	L7n.
o.	I've been accepting the possibility that I might have an altered gene.	1	2	3	4	L7o.
p.	I've been expressing my negative feelings.	1	2	3	4	L7p.
q.	I've been trying to find comfort in my religion or spiritual beliefs.	1	2	3	4	L7q.
r.	I've been learning to live with the possibility that I have an altered gene.	1	2	3	4	L7r.
s.	I've been thinking hard about what steps to take.	1	2	3	4	L7s.
t.	I've been praying or meditating.	1	2	3	4	L7t.
u.	I've been making fun of the situation.	1	2	3	4	L7u.

The following items are to be answered only by those women who are married or living with a partner.

☐ If not married or living with a partner skip to the Mood section, directly below.

		<i>I haven't been doing this at all</i>	<i>I've been doing this a little bit</i>	<i>I've been doing this some</i>	<i>I've been doing this a lot</i>	
v.	I've been denying or hiding my anger around my spouse/partner.	1	2	3	4	Lv.
w.	I've been denying or hiding my worries around my spouse/partner.	1	2	3	4	Lw.
x.	I've been avoiding talking about my problems around my spouse/partner.	1	2	3	4	Lx.
y.	I've acted more positive around my spouse/partner than I feel.	1	2	3	4	Ly.

MOOD SECTION

1. In the **past 6 months**, have you had two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun? (1) ☐ Yes (5) ☐ No (Skip to Question 2) I12.
 - 1a. If there was such a two-week period in the **past 6 months**, did your work or relationships suffer? I12a.
(1) ☐ Yes (5) ☐ No
 - 1b. If there was such a two-week period in the **past 6 months**, did you get counseling or psychotherapy? I12b.
(1) ☐ Yes (5) ☐ No
 - 1c. If there was such a two-week period in the **past 6 months**, did you get medication for this condition? I12c.
(1) ☐ Yes (5) ☐ No
2. Have you **ever in your lifetime** had two weeks or more when nearly every day you felt sad, blue, or depressed or in which you lost all interest in things like work or hobbies or things you usually liked to do for fun? (1) ☐ Yes (5) ☐ No (Skip to Question 3, next page) I14
 - 2a. If there was such a two-week period, did your work or relationships suffer? I14a.
(1) ☐ Yes (5) ☐ No
 - 2b. If there was such a two-week period, did you get counseling or psychotherapy? I14b.
(1) ☐ Yes (5) ☐ No
 - 2c. If there was such a two-week period, did you get medication for this condition? I14c.
(1) ☐ Yes (5) ☐ No
3. Are you **currently** receiving counseling, psychotherapy or medication for depression or emotional problems? I13.
(1) ☐ Yes (5) ☐ No

Symptoms of Strain Section

LISTED BELOW ARE SOME SYMPTOMS OF STRAIN THAT PEOPLE SOMETIMES HAVE. *Please Read Each One Carefully And Check The Answer Which Best Reflects How Much That Symptom Has Bothered You During the **Past Three Months**.*

		<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Extremely</u>	
1.	Suddenly scared for no reason	1	2	3	4	K1.
2.	Feeling fearful	1	2	3	4	K2.
3.	Faintness, dizziness, or weakness	1	2	3	4	K3.
4.	Nervousness or shakiness inside	1	2	3	4	K4.
5.	Heart pounding or racing	1	2	3	4	K5.
6.	Trembling	1	2	3	4	K6.
7.	Feeling tense or keyed up	1	2	3	4	K7.
8.	Headaches	1	2	3	4	K8.
9.	Spells of terror or panic	1	2	3	4	K9.
10.	Feeling restless, can't sit still	1	2	3	4	K10.
11.	Feeling low in energy--slowed down	1	2	3	4	K11.
12.	Blaming yourself for things	1	2	3	4	K12.
13.	Crying easily	1	2	3	4	K13.
14.	Loss of sexual interest or pleasure	1	2	3	4	K14.
15.	Poor appetite	1	2	3	4	K15.
16.	Difficulty falling asleep, staying asleep	1	2	3	4	K16.
17.	Feeling hopeless about the future	1	2	3	4	K17.
18.	Feeling blue	1	2	3	4	K18.
19.	Feeling lonely	1	2	3	4	K19.
20.	Feeling trapped or caught	1	2	3	4	K20.
21.	Worrying too much about things	1	2	3	4	K21.
22.	Feeling no interest in things	1	2	3	4	K22.
23.	Thoughts of ending your life	1	2	3	4	K23.
24.	Feeling everything is an effort	1	2	3	4	K24.
25.	Feelings of worthlessness	1	2	3	4	K25.

Relationships Section

1. Is there anyone in your life with whom you can share your most private feelings without holding back?

C21.

(1) ☐ Yes (5) ☐ No

Please complete the following questions only if you are married or living with a partner. If you are not married or living with a partner, please check the box and skip to Background Information Section on page 14.

Not married or living with a partner ☐

2. If married, can you share your most private feelings with your spouse without holding back?

C21a.

(1) ☐ Yes (5) ☐ No

3. If married, is there anyone besides your spouse with whom you can share your most private feelings without holding back?

C21b.

(1) ☐ Yes (5) ☐ No

First, we would like to ask you some questions about your spouse/partner's involvement in your health care.

4. Did your spouse/partner attend individual, family or group sessions to become informed about your risk for breast cancer and what can be done?

H36.

Yes (1) ☐ No (5) ☐

5. How much contact did your spouse/partner have with medical personnel concerning your family's risk for breast cancer and what can be done about it?

H37.

Very Little
or None

1

2

3

4

5

6

A Lot
7

6. Do you feel your spouse/partner is adequately informed concerning your family's risk for breast cancer and what can be done about it?

H38.

Not at All

1

2

3

4

5

6

Very Much
7

7. To what extent are you satisfied with your spouse's/partner's involvement in your health care?

H39.

Not at All Very Much
1 2 3 4 5 6 7

8. How much have you discussed results of your genetic testing with your spouse/partner?

B104a.

Not at All	Very Little	Some	A Lot
1	2	3	4

9. When you have these discussions, who generally initiates them?

B104b.

You	Your Spouse	Equally
1	2	3

10. How satisfied are you with these discussions?

B104c.

Not at All	A Little	Somewhat	A Great Deal
1	2	3	4

Second, we would like to ask you some questions about your marriage.

11. Most people have disagreements in their relationships. Please indicate by circling the number that represents the extent of agreement or disagreement experienced between you and your spouse/partner **DURING THE PAST MONTH.**

		<i>Always Agree</i>	<i>Almost Always Agree</i>	<i>Occasionally Disagree</i>	<i>Frequently Disagree</i>	<i>Almost Always Disagree</i>	<i>Always Disagree</i>
a.	Religious matters	1	2	3	4	5	6
b.	Demonstration of affection	1	2	3	4	5	6
c.	Sex relations	1	2	3	4	5	6
d.	Conventionality (correct or proper behavior)	1	2	3	4	5	6
e.	Making major decisions	1	2	3	4	5	6
f.	Career decisions	1	2	3	4	5	6

H3.

H4.

H6.

H7.

H12.

H15.

		<i>All of the time</i>	<i>Most of the time</i>	<i>More often than most</i>	<i>Occasionally</i>	<i>Rarely</i>	<i>Never</i>
12.	How often do you discuss or have you considered divorce, separation, or terminating your relationship?	1	2	3	4	5	6
13.	Do you ever regret that you married (or lived together)?	1	2	3	4	5	6
14.	How often do you and your partner quarrel?	1	2	3	4	5	6
15.	How often do you and your spouse/partner "get on each other's nerves?"	1	2	3	4	5	6

H16.

H20.

H21.

H22.

		<i>All of Them</i>	<i>Most of Them</i>	<i>Some of Them</i>	<i>Very few of Them</i>	<i>None of Them</i>
16.	Do you and your spouse/partner engage in outside interests together?	1	2	3	4	5

H24.

How often would you say the following events occur between you and your spouse/partner?

		<i>Never</i>	<i>Less than once a month</i>	<i>About twice a month</i>	<i>About twice a week</i>	<i>Once a day</i>	<i>More Often</i>
17.	Have a stimulating exchange of ideas	1	2	3	4	5	6
18.	Calmly discuss something	1	2	3	4	5	6
19.	Work together on a project	1	2	3	4	5	6

H25.

H27.

H28.

20. Considering **only the positive feelings** you have towards your spouse/partner, and **ignoring the negative ones**, please rate how positive these feelings are:

H33.

Not At All Positive								Extremely Positive	
1	2	3	4	5	6	7	8	9	10

21. Considering **only the negative feelings** you have towards your spouse/partner, and **ignoring the positive ones**, please rate how negative these feelings are:

H34.

Not At All Negative								Extremely Negative	
1	2	3	4	5	6	7	8	9	10

Background Information Section

1. Date of Birth _____ Month _____ Day _____ Year A1.

2. Ethnic Background: White ☐ 1 Black ☐ 4 A2.
 Hispanic ☐ 2 Asian ☐ 5
 Native American ☐ 3 Other ☐ 6

3. Religion: Catholic ☐ 1 Protestant ☐ 4 A3.
 Jewish ☐ 2 Buddhist ☐ 5
 Muslim ☐ 3 Other ☐ 6
 None ☐ 7

3a. How often do you attend religious services? A3a.

☐ 1 Less Than Once a Month ☐ 5 A Few Times A Month or More

3b. How important are religious and spiritual beliefs in your life? A3b.

Not at All Very Important
 1 2 3 4 5

4. Are you currently (please check one)? A4.

1 ☐ Single 4 ☐ Separated
 2 ☐ Married 5 ☐ Divorced
 3 ☐ Not married, but living in a steady, marriage-like relationship 6 ☐ Widowed

5. If you are currently married, what was the date of your current marriage? A5.
 (Month/ Year) _____

5a. Is this your first marriage? (1) ☐ Yes (5) ☐ No A5a.

6. How many children do you have? _____ A6.

6a. Number of children living at home? _____ A6a.

6b. Number who are under age 6? _____ A6b.

6c. Number of Daughters? _____ A6c.

7. Do you plan to have more children? (1) ☐ Yes (5) ☐ No (3) ☐ Undecided A12.
- 7a. If yes, how many more children? _____ A12a.
8. Are you currently working for pay outside the home? A7.
- (1) ☐ Yes (5) ☐ No
9. If yes, about how many hours per week are you working for pay? A8.
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Less than 10 | 10-20 | 21-30 | 31-40 | 41 or more |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (1) | (2) | (3) | (4) | (5) |
10. What is the highest level of education you have completed? (Please Check one) A9.
- | | |
|---|--|
| 1 <input type="checkbox"/> Less than 9th grade | 5 <input type="checkbox"/> Completed college |
| 2 <input type="checkbox"/> Dropped out of high school | 6 <input type="checkbox"/> Some graduate or professional training |
| 3 <input type="checkbox"/> Completed high school | 7 <input type="checkbox"/> Completed graduate or professional training |
| 4 <input type="checkbox"/> Some college | |

The following two questions are optional, but we hope that you will provide this information.

11. What is your household's total income? (Please Check one) A10.
- | | | |
|---|---|--|
| (1) <input type="checkbox"/> Less than \$10,000 | (4) <input type="checkbox"/> \$30,000 to \$39,999 | (7) <input type="checkbox"/> \$60,000 to \$69,999 |
| (2) <input type="checkbox"/> \$10,000 to \$19,999 | (5) <input type="checkbox"/> \$40,000 to \$49,999 | (8) <input type="checkbox"/> Greater than \$69,999 |
| (3) <input type="checkbox"/> \$20,000 to \$29,999 | (6) <input type="checkbox"/> \$50,000 to \$59,999 | |
12. How many people (adults and children) does this income support? _____ A11.

Thank You Very Much For Your Participation!

Participant Name: _____

TELEPHONE CONTACT ATTEMPTS

Date	Time	Outcome	Comments

Hello. May I please speak to [participant's name]?

My name is [caller's name]. I am calling from the Genetic Testing Study at the University of Pennsylvania. Recently we mailed you a letter notifying you that your genetic testing results are available, along with a questionnaire to complete as part of our ongoing study. We haven't heard back from you, and just wanted to check in to see that you received the letter, and to answer any questions you may have about the study.

 IF NEEDS ANOTHER LETTER &/OR QUESTIONNAIRE:

Would it be alright with you if we sent another letter and questionnaire?

IF YES: [confirm address]: _____

Where are you in your decision about whether or not to get the results of your genetic testing?

- ☐ 1. DECIDED NOT TO GET RESULTS
- ☐ 2. DECIDED TO GET RESULTS, BUT SOMETIME IN THE FUTURE
- ☐ 3. DECIDED TO GET RESULTS, AWAITING COUNSELING NOW
- ☐ 4. UNDECIDED; STILL THINKING ABOUT IT
- ☐ 5. ALREADY GOT RESULTS
- ☐ 6. NOT PLANNING TO PARTICIPATE ANY LONGER

1. DECIDED NOT TO GET RESULTS

Would you mind sharing your reasons why you decided not to get your test results?

We appreciate your participation in this study, and respect your decision not to get your results. We would like to hear from women who choose not to get results, as well as from those who do. May we send you a questionnaire to complete for us?

2. DECIDED TO GET RESULTS, BUT SOMETIME IN THE FUTURE:

Would you mind sharing the reasons you decided to wait to get results?

When you do decide that you're ready to get your results, you can contact us. Do you still have the contact information? (Kathy Calzone: 215-349-8141; or Melissa Racioppo: 215-662-4738) In the meantime, may we send you a questionnaire to complete for our ongoing study, while you decide about when to get results?

3. DECIDED TO GET RESULTS, AWAITING COUNSELING NOW:

Have you already received your genetic counseling? Do you have any questions about what happens next in the process?

4. UNDECIDED; STILL THINKING ABOUT IT:

Would you mind sharing your thoughts about testing? What are the factors that are most important in deciding whether or not to get results?

Do you feel that the genetic testing results would change the way you approach your health care?

Are there other things going on in your life right now that make it difficult to make a decision about getting test results?

Please remember that you can contact us at the University if you do decide to get your test results sometime in the future. In the meantime, may we send you a questionnaire to complete for our ongoing study, regardless of what you decide about getting results?

5. ALREADY GOT RESULTS:

When did you get your results? And from whom did you receive them? Thank you, and thank you for contributing your time and energy to this study.

Date received results:
Who delivered results:

We're interested in knowing how the process of testing and results-disclosure has gone for people. May we send you a questionnaire to complete for us that asks about your experiences with testing?

Confirm address:

[CHECK ANDREA MAILING LIST; IF GOT RESULTS BUT NO RESPONSE TO QUESTIONNAIRE, THEN SEND NEW RETROSPECTIVE QUESTIONNAIRE]

6. IF NOT PLANNING TO PARTICIPATE ANY LONGER:

May I ask why you would prefer not to participate any longer in the study?

IF FRUSTRATED WITH THE PROCESS: The process has taken longer than any of us anticipated. As new mutations have been discovered, we've decided to re-run some of the testing to be sure the results we give are accurate and up-to-date. Also, the testing technology has been developing along with the discoveries in the genes themselves, and this has delayed results as well. We certainly appreciate your patience during this process, and understand the wait has been frustrating.

Do you have any other questions about the study, or receiving your test results?

Thank you very much for your time, and for your help with this project. If you have questions in the future, please feel free to call Kathy Calzone at (215) 349-8141, or Melissa Racioppo at (215) 662-4738.